U.S. FOOD & DRUG ADMINISTRATION

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

Selection Criteria:

Product Name:				
Product Active Ingredient:				
Active Ingredient:	[HYDROXYCHLOROQUINE,HYDROXYCHLOROQUINE DIPHOSPHATE,HYDROXYCHLOROQUINE SULFATE]			
Active Moiety:				
FDA Received Date:	From:	01-Feb-2020	To:	09-Jun-2020
MedDRA® Version* :	23.0			
Total Cases**:	6900			
Number of Pages:	4885			

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

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

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	15854681	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633525-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rabeprazole Sodium			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	16851800	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2937832-00		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug	Humira			S	Subcutaneous			Not Reported

Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Arava	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rapamune	S	Unknown	Not Reported
	Tacrolimus	S	Oral	Not Reported
	Tacrolimus	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Hydroxyquinoline Sulfate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Neoral	S	Unknown	Not Reported
	Imuran	C	Unknown	Not Reported
	Azathioprine	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358261	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3256489-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Retinopathy	Humira			S	Subcutaneous	10 Months		Not Reported
	Plaquenil			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Methotrexate			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358339	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531525		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Desoximetasone			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358340	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531538		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Remicade		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358348	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531587			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358349	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530929			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Hepatic Cirrhosis; Synovitis; Treatment Failure; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358358	EXPEDITED (15-DAY)		OT	CA-ROCHE-2532601			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358674	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533819			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported

Orencia	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral		Not Reported
Desoximetasone	C	Unknown		Not Reported
Methotrexate	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358677	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533827			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Desoximetasone			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358682	EXPEDITED (15-DAY)		OT	CA-ROCHE-2534194			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Celebrex			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2020	11310374	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2015073223		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthritis; Blood Creatinine Decreased; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Discharge; Eye Disorder; Eye Operation; Eye Pain; Fatigue; Glaucoma; Haematocrit Decreased; Haemoglobin Decreased; Headache; Inflammation; Lacrimation Increased; Lymphocyte Count Increased; Monocyte Count Increased; Nasopharyngitis; Nausea; Neutrophil Count Decreased; Ocular Procedural Complication;	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Acetaminophen			S	Oral	65 Milligram		Not Reported
	Acetaminophen			S	Unknown	Unk		Not Reported
	Acetaminophen			S	Oral	65 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	520 Milligram, Q4wk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	520 Milligram		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, 4 Times/Wk		Not Reported

Optic Neuritis; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Tinnitus; Vision Blurred; White Blood Cell Count Decreased	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Prednisone	S	Unknown	7.5 Milligram	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Apo Hydromorphone	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Apo-Acetaminophen	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydromorphone	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qd	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	15.5 Unk	Not Reported
	Hydromorphone Hydrochloride	S	Unknown	Unk	Not Reported
	Calcium Folinate	S	Unknown	5 Milligram	Not Reported
	Humira	C	Subcutaneous	Unk	Not Reported
	Humira	C	Unknown	Unk	Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	C	Unknown	Unk	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported

Remicade	C	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	C	Oral	50 Milligram	Not Reported
Diphenhydramine Hydrochloride	C	Unknown	Unk	Not Reported
Fosavance	C		Unk Unk, Qwk	Not Reported
Hydrocortisone	C	Intravenous (not otherwise specified)	250 Milligram	Not Reported
Hydrocortisone	C	Unknown	Unk	Not Reported
Hyzaar	C		12.5 Milligram, Qd	Not Reported
Hyzaar	C	Unknown	Unk	Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
Methylprednisolone	C	Unknown	Unk	Not Reported
Alendronate Sodium;Colecalciferol	C		Unk Unk, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2020	11490879	NON-EXPEDITED		HO, LT, OT	CA-AMGEN-CANSP2015093585		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric	Enbrel			S	Subcutaneous	12.5 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk		Amgen
	Enbrel			S	Subcutaneous	12.5 Milligram, Qd		Amgen
	Enbrel			S	Unknown	25 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	1.5 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	25 Milligram		Amgen
	Enbrel			S	Unknown	12.5 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	4 Dosage Form, Qwk		Amgen
	Enbrel			S	Subcutaneous	12.5 Milligram, 4 Times/Wk		Amgen
	Enbrel			S	Subcutaneous	25 Milligram, Bid		Amgen
	Enbrel			S	Unknown	25 Milligram		Amgen

Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Short Stature; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Cyclical	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Q2wk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram/Kilogram, Qd	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Immune Globulin Intravenous (Human)	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram, Qwk	Not Reported
	Infliximab	S	Unknown	5 Milligram	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram Cyclical	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Milligram	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	1 Dosage Form, Qwk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram	Not Reported

Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Adalimumab	S			Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Q2wk	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Q2wk	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter 12 Every 2 Weeks	Not Reported
Methotrexate	S	Subcutaneous	1 Dosage Form, Qwk	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Qwk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Milligram, Qmo	Not Reported
Orencia	S		250 Milligram, Qmo	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Milligram, Qmo	Not Reported
Orencia	S	Intravenous (not otherwise specified)	1 Dosage Form, Qmo	Not Reported
Prednisone	S	Oral	3 Milligram, Bid	Not Reported
Prednisone	S	Oral	5 Milligram, Bid	Not Reported
Prednisone	S	Oral	1.3 Milligram, Bid	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	2 Dosage Form, Qd	Not Reported
Prednisone	S	Oral	3 Milligram, Bid	Not Reported
Anakinra	S	Subcutaneous	50 Milligram, Qd	Not Reported
Anakinra	S	Unknown	Unk, Qd	Not Reported
Anakinra	S	Subcutaneous	Unk	Not Reported
Anakinra	S	Subcutaneous	1 Dosage Form, Qd	Not Reported

Anakinra	S	Subcutaneous	50 Milligram, Qd	Not Reported
Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form, Qd	Not Reported
Triamcinolone	S	Subcutaneous	25 Milligram, Q2wk	Not Reported
Triamcinolone	S	Unknown	Unk	Not Reported
Abatacept	S	Intravenous (not otherwise specified)	250 Milligram, Qmo	Not Reported
Abatacept	S			Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
Immunoglobulin (Immunoglobulin Human Normal)	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
Immunoglobulin (Immunoglobulin Human Normal)	S	Unknown	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Naproxen	S			Not Reported
Methotrexate Sodium	S	Unknown	Unk, Qwk	Not Reported
Methotrexate Sodium	S			Not Reported
Apo-Naproxen	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Oral	3 Milligram, Bid	Not Reported
Apo-Prednisone	S	Oral	5 Milligram, Bid	Not Reported
Apo-Prednisone	S	Oral	5 Milligram, 2 Times/Wk	Not Reported
Apo Triamcinolone Aq	S	Intra-articular	Unk	Not Reported
Apo Triamcinolone Aq	S			Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unk	Not Reported
Triamcinolone Acetonide	S	Oral	5 Milligram, Qd	Not Reported
Triamcinolone Acetonide	S			Not Reported
Triamcinolone Acetonide	S			Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Milligram/Kilogram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	1 Dosage Form, Qd	Not Reported
Gammagard	S	Intravenous (not otherwise specified)	70 Gram	Not Reported

	Naproxen Sodium	S	Unknown	Unk		Not Reported
	Folic Acid	C		Unk		Not Reported
	Triamcinolone Hexacetonide	C	Unknown	Unk		Not Reported
	Triamcinolone Hexacetonide	C	Intra-articular	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2020	12635667	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016101720		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Ill-Defined Disorder; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Celebrex			S	Oral	200 Milligram, Bid		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk (Solution)		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo Celecoxib			S	Oral	200 Milligram, Bid		Not Reported
	Celecoxib			S	Oral	200 Milligram, Bid		Not Reported
	Toradol			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	7-10 Milligram, Unk		Not Reported
	Tramadol			C	Unknown	100 Milligram, As Necessary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2020	14321179	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017110785		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Pain; Spinal Compression Fracture; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2020	16120605	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019044829			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Enbrel			S	Unknown	Unk Unk, Qwk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Bid		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2020	17358981	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020015573		40 YR	Male	CAN

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	12302836	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016051354		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event; Off Label Use; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not	8 Milligram/Kilogram		Not Reported

			otherwise specified)		
	Arava	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qwk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	12579837	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016355316			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Ulcer; Inflammation; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Pruritus; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, 4 Times/Wk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk Unk, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	13908882	NON-EXPEDITED		HO, LT, OT	CA-AMGEN-CANSP2017127671		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported

Gold	S	Unknown	Unk		Not Reported
Apo-Leflunomide	S	Unknown	Unk		Not Reported
Apo-Leflunomide	S				Not Reported
Ilaris	S	Intravenous (not otherwise specified)	Unk		Not Reported
Ilaris	S	Subcutaneous	Unk		Not Reported
Ilaris	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S				Not Reported
Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
Sodium Aurothiomalate	S				Not Reported
Rituximab	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	14421683	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018006742		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Bactrim			S	Unknown			Not Reported

	Xeljanz			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	14868417	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2018061435		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Arthralgia; Arthropathy; Cholecystectomy; Contraindicated Product Administered; Dermatitis; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Fatigue; Gallbladder Disorder; Gastric Disorder; Groin Pain; Hip Surgery; Joint Swelling; Miliaria; Off Label Use; Pancreatitis; Photosensitivity Reaction; Pruritus Allergic; Rheumatoid Arthritis; Sleep Disorder; Stomatitis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	11:1 Milligram, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Morphine			S	Unknown	Unk		Not Reported
	Morphine			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	200 Milligram, Q12h		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Citalopram			C		10 Milligram, Qd		Not Reported
	Pantoloc			C		40 Milligram, Bid		Not Reported
	Pantoloc			C				Not Reported
	Prednisone			C	Unknown	10 Milligram, Qd		Not Reported
	Celebrex			C	Unknown	200 Milligram, Bid		Not Reported
	Lorazepam			C	Unknown	1 Milligram, Qhs (At Bedtime)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	16055007	EXPEDITED (15-DAY)		OT	CA-ROCHE-2277556		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	16084291	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022664		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort; Adverse Drug Reaction; Adverse Event; Alopecia; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hip	Diclofenac Sodium			S	Unknown			Actavis
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Oral	2 Gram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Prednisone			S	Unknown			Actavis
	Prednisone			S				Actavis
	Paracetamol			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported
	Arava			S	Oral			Not Reported
	Arava			S				Not Reported

Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Pain; Pain; Pemphigus; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S			Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Cimzia Single-Use Prefilled Syringe	S			Not Reported
	Cortisone	S	Oral		Not Reported
	Cortisone	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Cutaneous		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S			Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Subcutaneous		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Apo-Hydroxychloroquine	S	Unknown		Not Reported
	Apo-Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Apo-Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Plaquenil/00072603/	S	Oral		Not Reported
	Plaquenil/00072603/	S			Not Reported
	Reactine//Cetirizine Hydrochloride	S	Unknown		Not Reported
	Reactine//Cetirizine Hydrochloride	S			Not Reported
	Remicade	S	Intravenous (not		Not Reported

			otherwise specified)		
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S			Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	500 Milligram Daily;	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Apo-Prednisone	S			Not Reported
	Cetirizine Hydrochloride W/Pseudoephedrine	S	Unknown		Not Reported
	Hydrocortisone Acetate	S	Subcutaneous		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Topicort	S	Subcutaneous		Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	16129066	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-027216		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Off Label Use; Pain In Extremity; Peripheral Swelling;	Orencia			S	Unknown			Bristol Myers Squibb
	Amlodipine Besilate			S	Oral	5 Milligram, Qd		Not Reported
	Asacol			S	Oral	800 Milligram, Tid		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Mesalazine			S	Oral	800 Milligram, Tid		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	50 Milligram, Qwk		Not Reported

Vitamin D Deficiency	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown		Not Reported
	Amlodipine Besilate	C	Oral	5 Milligram, Qd	Not Reported
	Atacand Plus	C	Oral	Unk, Qd	Not Reported
	Bisoprolol Fumarate	C	Oral	2.5 Milligram	Not Reported
	Depo-Medrol	C	Intra-articular	120 Milligram	Not Reported
	Depo-Medrol	C	Intramuscular	120 Milligram	Not Reported
	Ferrous Gluconate	C	Oral	300 Milligram	Not Reported
	Folic Acid	C	Oral	5 Milligram	Not Reported
	Omega Allergenic Extracts	C	Unknown		Not Reported
	Tylenol	C	Unknown	500 Milligram	Not Reported
	Vitamin D3	C	Unknown	1000 International Unit, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	16201898	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019058114			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Sulfasalazine	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Naproxen	C		500 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	16443920	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033823		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cataract; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Metformin			S	Unknown	500 Milligram, Two Times A Day		Aurobindo
	Desoximetasone			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Altace			C	Unknown	5 Milligram, Once A Day		Not Reported
	Asa			C	Unknown	81 Milligram, Once A Day		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	1 Dosage Form, 6 Every 1 Week		Not Reported
	Methotrexate			C	Oral	15 Milligram, Once A Day		Not Reported
	Rosuvastatin Calcium			C	Unknown	20 Milligram, Once A Day		Not Reported
	Vitamin D			C	Unknown	Unk		Not Reported
	Omega 3			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	16521599	EXPEDITED (15-DAY)		OT	CA-ROCHE-2346118		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	16829773	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1109222		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Bisoprolol			S	Unknown			Duramed
	Bisoprolol			S	Unknown			Duramed
	Celecoxib			S	Oral	200 Milligram Daily;		Teva
	Diclofenac W/Misoprostol			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Levofloxacin			S	Unknown			Teva
	Methotrexate			S				Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Norfloxacin			S	Unknown			Not Reported
	Bisoprolol Fumurate			S	Unknown			Duramed

	Levofloxacin Hemihydrate	S	Unknown		Teva
	Methotrexate Sodium	S	Unknown		Barr
	Apo-Bisoprolol	S	Unknown		Not Reported
	Apo-Norflox	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Arthrotec	S	Unknown		Not Reported
	Ceclor	S	Unknown		Not Reported
	Celebrex	S	Oral		Not Reported
	Celebrex	S	Oral		Not Reported
	Demerol	S	Unknown		Not Reported
	Erythro Base	S	Unknown		Not Reported
	Erythromycin	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Lyrica	S	Unknown		Not Reported
	Meperidine	S	Unknown		Not Reported
	Meperidine Hcl	S	Unknown		Not Reported
	Plaquenil	S	Oral	400 Milligram Daily;	Not Reported
	Plaquenil	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Erythromycin	S	Unknown		Not Reported
	Metronidazole	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17261096	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP005141			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label	Doxycycline			S	Unknown	50 Mg, Unk		Apotex

Use; Rheumatoid Arthritis	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Hydroxychloroquine	S	Unknown	200.0 Mg, Unk	Apotex
	Leflunomide	S	Unknown	10 Mg, Qd	Apotex
	Leflunomide	S	Unknown	20 Mg, Qd	Apotex
	Doxycycline Hyclate	S	Unknown	50 Mg, Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	50 Mg, Q.M.T.	Not Reported
	Prednisone	C	Unknown	10.0 Mg, Qd	Not Reported
	Methotrexate	C	Unknown	25.0 Mg, Unk	Not Reported
	Xeljanz	C	Unknown	50 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17270951	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP005142			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Doxycycline			S	Unknown	50 Mg, Unknown		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	10.0 Mg, Qd		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Simponi			C	Subcutaneous	Unk		Not Reported
	Xeljanz			C	Unknown	5.0 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359168	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005580			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Bifidobacterium Bifidum			C	Unknown	Unk		Not Reported
	Loperamide			C	Oral	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk, Tid		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359226	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533869		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Kineret	S	Subcutaneous	Not Reported
	Kineret	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Naproxen	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Other	Not Reported
	Triamcinolone Hexacetonide	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359267	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533849		57 YR	Male	CAN

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

					otherwise specified)					
	Desoximetasone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359279	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533864			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gammagard			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous	100 Mg Per Syringe Single Use, Preservative- Pre Filled Syringes		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Subcutaneous			Not Reported

	Triamcinolone Acetonide	S	Unknown		Not Reported
	Triamcinolone Acetonide	S			Not Reported
	Triamcinolone Acetonide	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359286	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533836			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Immunoglobulin Human Normal			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Immunoglobulin Human Normal			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Kineret			S	Subcutaneous	Solution Subcutaneous, 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Prednisone	S	Oral			Not Reported
Prednisone	S	Oral			Not Reported
Sulfasalazine	S	Oral			Not Reported
Triamcinolone	S	Other			Not Reported
Triamcinolone Hexacetonide	S	Intra-articular	Suspension Intraarticular		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359348	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532707			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone Acetonide			S	Intra-articular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359365	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532680			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359389	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532679			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Joint	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Gp2013			S	Intravenous (not otherwise specified)	Therapy Duration: 1.0 Months		Not Reported
	Gp2013			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported

Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use In Unapproved Indication; Product Use Issue; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Enbrel	S	Subcutaneous	Therapy Duration: 610.0 Days	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Therapy Duration: 4.0 Years	Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Therapy Duration: 2.0 Months	Not Reported
	Infliximab	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	Therapy Duration: 5.0 Years	Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359475	EXPEDITED (15-DAY)		HO	CA-ROCHE-2531147		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Nausea;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Occlusive dressing technique			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported

Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Oxycontin	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	Not Reported
	Actonel	C		Not Reported
	Vitamin C [Ascorbic Acid]	C		Not Reported
	Biotin	C		Not Reported
	D-Alpha Tocopherol	C		Not Reported
	Ergocalciferol	C		Not Reported
	Esomeprazole	C		Not Reported
	Ferrous Fumarate	C		Not Reported
	Ferrous Gluconate	C		Not Reported
	Folic Acid	C		Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C		Not Reported
	Loperamide	C		Not Reported
	Nasonex	C		Not Reported
	Nicotinamide	C		Not Reported
	Nortriptyline	C		Not Reported
	Pantoprazole	C		Not Reported
	Prednisone	C		Not Reported
	Pyridoxine	C		Not Reported
	Retinol Palmitate	C		Not Reported
	Riboflavin	C		Not Reported
	Sodium Ascorbate	C		Not Reported
	Thiamine	C		Not Reported
	Thiamine Hydrochloride	C		Not Reported
	Trazodone	C		Not Reported
	Tylenol	C		Not Reported
	Vitamin A [Retinol]	C		Not Reported
	Vitamin B12 [Cyanocobalamin]	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359490	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-GSH201904-001246			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster; Meningitis Aseptic	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd (Daily Administration)		Concordia
	Micardis			C		Unk		Not Reported
	Thyradin S			C		Unk		Not Reported
	Baktar			C		Unk		Not Reported
	Baktar			C				Not Reported
	Takepron			C		Unk		Not Reported
	Takepron			C				Not Reported
	Onealfa			C		Unk		Not Reported
	Onealfa			C				Not Reported
	Bonalon			C		Unk		Not Reported
	Bonalon			C				Not Reported
	Persantin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359581	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2543863-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Pruritus; Synovitis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359641	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531537		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Fatigue; Hand Deformity; Headache; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359679	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-006501			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

	Fosamax	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359682	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0585			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359689	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0594			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359691	EXPEDITED (15-DAY)		HO	CA-ROCHE-2531148		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Oxycontin	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Actonel	C		Not Reported
	Aclasta	C		Not Reported
	Esomeprazole	C		Not Reported
	Ferrous Gluconate	C		Not Reported
	Genteal [Carmellose Sodium;Hypromellose]	C		Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C		Not Reported
	Nasonex	C		Not Reported
	Esomeprazole	C		Not Reported
	Nortriptyline	C		Not Reported
	Prednisone	C		Not Reported
	Trazodone	C		Not Reported
	Tylenol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359693	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202001000512			Unknown	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359849	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532669			Unknown	CAN

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

Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Infliximab	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Kineret	S	Subcutaneous	100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Naproxen	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Triamcinolone	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360047	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533775		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported

Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Sunconjunctival	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360147	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-092402		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Colitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Vitamin D Deficiency	Amlodipine			S	Oral	5 Milligram		Aurobindo
	Methotrexate			S	Subcutaneous	25 Milligram, One Every 2 Weeks		Not Reported
	Asacol			S	Oral	800 Milligram, 3 Times A Day		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported

Enbrel	S	Subcutaneous	50 Milligram		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Plaquenil	S	Unknown	Unk		Not Reported
Amlodipine Besilate	C	Unknown	Unk		Not Reported
Atacand Plus	C	Unknown	Unk		Not Reported
Bisoprolol Fumarate	C	Unknown	Unk		Not Reported
Depo-Medrol	C	Unknown	Unk		Not Reported
Ferrous Gluconate	C	Unknown	Unk		Not Reported
Folic Acid	C	Unknown	Unk		Not Reported
Omega Allergenic Extracts	C	Unknown	Unk		Not Reported
Tylenol	C	Unknown	Unk		Not Reported
Vitamin D3	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360197	EXPEDITED (15-DAY)		OT	CA-ROCHE-2535489			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Cimzia Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360276	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533780			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sulfasalazine	S	Oral	Not Reported
	Acetaminophen And Codeine	C	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360307	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533782		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Swelling	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360344	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533783			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360441	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533784		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Nausea; Obesity; Septic Shock; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Kineret			S	Unknown	100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Triamcinolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360448	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533790			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Off Label Use; Rheumatoid	Actemra			S	Unknown			Not Reported

Arthritis	Arava		S	Oral	Not Reported
	Ciclosporin		S	Unknown	Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Imuran [Azathioprine]		S	Unknown	Not Reported
	Infliximab		S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360506	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0610			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360817	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531843		67 YR	Female	CAN

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

Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Arthrotec	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Imuran [Azathioprine]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17361304	EXPEDITED (15-DAY)		DE	US-GLENMARK PHARMACEUTICALS-2020GMK045822		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide	Naproxen			S	Oral	Unk		Glenmark
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Ibuprofen			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17362077	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020043730			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug	Enbrel			S	Unknown			Pfizer

Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Methotrexate Sodium	S	Unknown		Pfizer
	Sulfasalazine	S	Unknown	500 Mg, 2x/Day	Pfizer
	Xeljanz	S	Unknown		Pfizer
	Actemra	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day	Not Reported
	Leflunomide	S	Unknown	10 Mg, 1x/Day	Not Reported
	Lyrica	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17362094	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005520			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17362158	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532892			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported

Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Anakinra	S	Subcutaneous	Not Reported
	Apo-Naproxen	S	Unknown	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gammagard	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone Acetonide	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17362159	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532688		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous			Not Reported

Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Methotrexate	S	Subcutaneous	Not Reported
	Naproxen	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Other	Not Reported
	Triamcinolone Hexacetonide	C	Intra-articular	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17362187	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020041070		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal	Enbrel			S	Subcutaneous	50 Mg, Monthly		Pfizer
	Methotrexate Sodium			S	Unknown	15 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Subcutaneous	162 Mg, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17362841	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1178156			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Drug	Ciprofloxacin			S	Unknown			Not Reported
	Clindamycin			S	Unknown			Actavis
	Enalapril			S	Unknown			Actavis
	Hydrochlorothiazide			S	Unknown			Ivax

Ineffective; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Malaise; Nausea; Rash	Losartan	S	Unknown	Teva
	Methotrexate	S	Unknown	Barr
	Moxifloxacin Hydrochloride	S	Unknown	Teva
	Pantoprazole Magnesium	S	Unknown	Teva
	Codeine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Biaxin	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Isoniazid	S	Unknown	Not Reported
	Keflex	S	Unknown	Not Reported
	Levaquin	S	Unknown	Not Reported
	Lopresor	S	Unknown	Not Reported
	Pariet	S	Unknown	Not Reported
	Penicillin	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Cipro	C	Unknown	Not Reported
	Esomeprazole	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported
	Hydroxyquinoline Sulfate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Saccharated Iron Oxide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17362927	EXPEDITED (15-DAY)		OT	CA-SA-2020SA003084			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Maculopathy; Retinopathy;	Plaquenil			S	Oral	400 Mg, Qd		Sanofi

Treatment Failure	Arava	S	Oral	20 Mg, Qd	Sanofi
	Myochrysine	S		Unk	Not Reported
	Methotrexate	S	Oral	15 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Qw	Not Reported
	Methotrexate	S	Oral	20 Mg, Qw	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Q4w	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Qw	Not Reported
	Enbrel	C	Subcutaneous	50 Mg, Qw	Not Reported
	Humira	C	Subcutaneous	40 Mg, Qow	Not Reported
	Prednisone	C		1 Mg, Qd (Prn)	Not Reported
	Prednisone	C		5 Qd (Prn)	Not Reported
	Prednisone	C		4 Mg, Qd (Prn)	Not Reported
	Prednisone	C		3 Mg, Qd (Prn)	Not Reported
	Prednisone	C		2 Mg, Qd (Prn)	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Codeine	C			Not Reported
	Morphine	C			Not Reported
	Demerol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17362930	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024485		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Off Label Use; Treatment Failure	Hydroxychloroquine Sulfate			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Tylenol			C				Not Reported

	Prednisone	C	5 Mg, Qd	Not Reported
	Prednisolone Acetate	C	5 Mg, Qd	Not Reported
	Leflunomide	C		Not Reported
	Desoximetasone	C	5 Mg, Qd	Not Reported
	Cyclobenzaprine	C	10 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363122	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023780			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Leflunomide			S		Unk		Sanofi
	Sarilumab			S		Unk		Sanofi
	Leflunomide			S		Unk		Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1.0 G		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Tocilizumab			S		Unk		Not Reported
	Tofacitinib			S		Unk		Not Reported
	Xeljanz			S		Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg		Not Reported
	Methotrexate			C		Unk		Not Reported

Rabeprazole Sodium	C	Oral	20 Mg, Qd		Not Reported
Sulfasalazine	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363123	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023722			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Plaquenil			S		400 Mg		Sanofi
	Arava			S				Sanofi
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Minocycline Hydrochloride			S				Not Reported
	Sulfasalazine			S				Not Reported
	Azathioprine			S		100 Mg		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S		5 Mg, Qd (2 Every 1 Days)		Not Reported
	Hydroxychloroquine			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363226	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533723			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Sublingual			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine		S	Unknown	Not Reported
	Infliximab		S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363232	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533732			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363250	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533735		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; Diarrhoea; Dizziness;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Drug Ineffective; Human Antichimeric Antibody Positive; Nausea; Obesity; Product Use In Unapproved Indication; Product Use Issue; Septic Shock; Vomiting	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Kineret	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363261	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532637			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Joint Destruction; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Subcutaneous	Therapy Duration:- 404.0 Days		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration:- 5.0 Years		Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

Count Increased; Product Use In Unapproved Indication; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Vascular Access Complication; White Blood Cell Count Increased	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363315	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533753		52 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363416	EXPEDITED (15-DAY)		OT	CA-ROCHE-2532632			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363643	EXPEDITED (15-DAY)		DS	CA-SA-2020SA024097			Female	CAN

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

Arthralgia; Drug Hypersensitivity; Drug Ineffective; Infection; Inflammation; Joint Swelling; Loss Of Personal Independence In Daily Activities	Hydroxychloroquine Sulfate	S			Sanofi
	Leflunomide	S			Sanofi
	Methotrexate	S			Not Reported
	Plaquenil	S			Sanofi
	Prednisone	S		10 Mg, Qd	Not Reported
	Sulfasalazine	S	Oral	1500 Mg, Bid	Not Reported
	Levothyroxine Sodium	S			Not Reported
	Leflunomide	S			Sanofi
	Orencia	S			Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Azathioprine	S			Not Reported
	Enbrel	S			Not Reported
	Etanercept	S		1 Mg, Qw	Not Reported
	Humira	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363905	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005936			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363959	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005958			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Diverticulitis; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	1500 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	10677800	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2014100610		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia;	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S				Amgen
	Aclasta			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported

Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Joint Swelling; Knee Arthroplasty; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Product Use In Unapproved Indication; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Operation; Spinal Stenosis; Treatment Failure	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S			Not Reported
	Sulfasalazine	S	Oral	2 Gram, Qd	Not Reported
	Tramacet	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	17.5 Mg - 25mg Every Week	Not Reported
	Methotrexate	S	Unknown	Unk, Qwk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	1 Dosage Form, Qd	Not Reported
	Tramadol/Acetaminophen	S	Oral	Unk	Not Reported
	Metformin	C	Unknown	5 Milligram, Qd	Not Reported
	Metformin	C	Unknown	500 Milligram, Bid	Not Reported
	Lorazepam	C		1 Milligram, Once Nightly	Not Reported
	Lorazepam	C		1 Milligram, Qd	Not Reported
	Nortriptyline Hydrochloride	C	Unknown	20 Milligram, Qd	Not Reported
	Vagifem	C	Unknown	Unk	Not Reported
	Premarin	C	Unknown	0.625 Milligram	Not Reported
	Vitamin D	C		Unk	Not Reported
	Calcium	C	Unknown	Unk	Not Reported
	Tylenol Arthritis Pain	C		Unk	Not Reported
	Actonel	C		35 Milligram, Qwk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Methylprednisolone Acetate	C	Intramuscular	40 Milligram, Qmo	Not Reported

Methylprednisolone Acetate	C	Subcutaneous	Unk, Qmo		Not Reported
Methylprednisolone Acetate	C				Not Reported
Depomedrol	C	Intramuscular	40 Mg, Qmo		Not Reported
Depomedrol	C	Subcutaneous	Unk Unk, Qmo		Not Reported
Depomedrol	C				Not Reported
Lyrica	C	Oral	150 Milligram, Bid		Not Reported
Nortriptyline	C	Unknown	Unk (Tablet And Capsule)		Not Reported
Nortriptyline	C				Not Reported
Risedronate Sodium	C	Unknown	35 Milligram, Qwk		Not Reported
Tylenol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	11231394	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015064666		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Vaccine; Condition Aggravated; Diarrhoea; Drug Ineffective; Fall; Hypersensitivity; Laryngeal Disorder; Larynx Irritation; Nausea; Product Use Issue; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Enbrel			S	Subcutaneous	Unk		Amgen
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Zostavax			S	Subcutaneous	Unk (Powder For Suspension)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	11515749	EXPEDITED (15-DAY)		HO, LT, OT	CA-PFIZER INC-2015293060		365 DAY	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthritis; Arthropathy; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use Issue; Psoriasis; Pyrexia;	Enbrel			S	Subcutaneous	12.5 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous	25 Mg, Every Two Week		Pfizer
	Enbrel			S	Subcutaneous	25 Mg, Unk		Pfizer
	Enbrel			S	Subcutaneous	25 Milligram		Pfizer
	Enbrel			S	Subcutaneous	12.5 Mg, 1x/Day		Pfizer
	Enbrel			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous	12.5 Mg, 4times/Wk		Pfizer
	Enbrel			S	Unknown	25 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	1.5 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	12.5 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	4 Dosage Form, Qwk		Pfizer
	Enbrel			S	Subcutaneous	25 Milligram, Bid		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Infliximab Hospira			S	Intravenous (not otherwise specified)	3 Mg/Kg, Weekly (1 Every 1 Week)		Not Reported
	Infliximab Hospira			S	Intravenous (not otherwise specified)	5 Mg/Dose, Unk		Not Reported
	Infliximab Hospira			S	Intravenous (not otherwise specified)	3 Mg/Kg, Cyclic (Once Every 6 Weeks)		Not Reported
	Infliximab Hospira			S	Unknown	Unk		Not Reported
	Infliximab Hospira			S	Intravenous (not otherwise specified)	3 Mg, Weekly (1 Every 1 Week(S))		Not Reported
	Infliximab Hospira			S	Unknown	3 Mg, Weekly		Not Reported
	Infliximab Hospira			S		5 Mg, Unk		Not Reported
	Methotrexate Sodium			S		15 Mg/M2, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	15 Mg/M2, Weekly		Unknown

Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Short Stature; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Methotrexate Sodium	S	Subcutaneous	15 Mg, Weekly	Unknown
	Methotrexate Sodium	S	Unknown	Unk	Unknown
	Methotrexate Sodium	S		15 Mg, 2x/Week	Unknown
	Methotrexate Sodium	S	Subcutaneous	15 Milligram/Sq. Meter, Q2wk	Unknown
	Methotrexate Sodium	S	Subcutaneous	15 Milligram/Sq. Meter 12 Every 2 Weeks	Unknown
	Methotrexate Sodium	S		Unk	Unknown
	Methotrexate Sodium	S	Unknown	1 Dosage Form, Qwk	Unknown
	Methotrexate Sodium	S	Subcutaneous	15 Milligram/Sq. Meter, Qwk	Unknown
	Sulfasalazine	S	Oral	250 Mg, Qd(1 Every 24 Hour(S))	Pfizer
	Sulfasalazine	S	Unknown	250 Mg, 1x/Day	Pfizer
	Sulfasalazine	S	Oral	1 Dosage Form, Qd	Pfizer
	Triamcinolone	S	Unknown	Unk	Unknown
	Triamcinolone	S		Unk	Unknown
	Triamcinolone	S		Unk	Unknown
	Infliximab	S	Unknown	3 Mg, Weekly	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	1 Dosage Form, Qwk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Unk	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Unk	Pfizer
	Triamcinolone Acetonide	S	Unknown	Unk	Pfizer
	Triamcinolone Acetonide	S	Oral	5 Milligram, Qd	Pfizer
	Triamcinolone Acetonide	S			Pfizer
	Hydroxychloroquine	S	Oral	5 Mg/Kg, 1x/Day (Daily)(1 Every 24 Hour(S))	Not Reported
	Hydroxychloroquine	S	Oral	5 Mg/Kg, Daily	Not Reported
	Hydroxychloroquine	S	Oral	Unk Unk, Qd (5.0)	Not Reported
	Hydroxychloroquine	S	Oral	1 Dosage Form, Qd	Not Reported

Naproxen	S	Unknown	Unk	Not Reported
Naproxen	S			Not Reported
Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	3 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	1.3 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	5 Mg, 2x/Week	Not Reported
Prednisone	S	Oral	3 Mg, 2x/Day	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	2 Dosage Form, Qd	Not Reported
Prednisone	S	Oral	3 Milligram	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Immunoglobulin Human Normal	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Immunoglobulin Human Normal	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Anakinra	S	Subcutaneous	50 Mg, 1x/Day (Daily) (1 Every 24 Hour(S))	Not Reported
Anakinra	S	Unknown	50 Mg, Weekly	Not Reported
Anakinra	S	Subcutaneous	Unk	Not Reported
Anakinra	S	Unknown	50 Mg, 1x/Day Qd	Not Reported
Anakinra	S	Subcutaneous	1 Dosage Form, Qd	Not Reported
Abatacept	S	Intravenous (not otherwise specified)	250 Mg, Monthly	Not Reported
Abatacept	S		250 Mg, Qmo	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Cyclic (2 Every 1 Week(S))	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Unk	Not Reported

Triamcinolone Hexacetonide	S	Unknown	Unk	Not Reported
Immunoglobulins Nos	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Immunoglobulins Nos	S	Intravenous (not otherwise specified)	3 Mg/Kg, Weekly	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Mg, Monthly (1 Every 1 Month (S))	Not Reported
Orencia	S	Unknown	250 Mg, Monthly Inhalation	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Mg, Unk	Not Reported
Orencia	S	Unknown	250 Mg, Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	1 Dosage Form, Qmo	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Weekly (1 Every 1 Week)	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, 2x/Week	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Unk	Not Reported
Actemra	S		280 Mg, Cyclical	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, 1x/Day Qd	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Qwk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Q2wk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Kineret	S	Subcutaneous	50 Mg, 1 Every 1 Day	Not Reported

Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
Apo-Naproxen	S	Unknown	Unk	Not Reported
Apo-Naproxen	S			Not Reported
Apo-Prednisone	S	Oral	3 Mg, 2x/Day(2 Every 1 Day(S))	Not Reported
Apo-Prednisone	S	Oral	5 Mg, 2x/Day(2 Every 1 Day(S))	Not Reported
Apo-Prednisone	S	Oral	5 Milligram, 2 Times/Wk	Not Reported
Apo Triamcinolone Aq	S	Unknown	Unk	Not Reported
Apo Triamcinolone Aq	S	Intra-articular	Unk	Not Reported
Gammagard	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Gammagard	S			Not Reported
Apo-Hydroxyquine	S	Oral	5 Mg, 1x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Mg, 1x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Mg/Kg, 1x/Day	Not Reported
Gamastan	S	Intramuscular	70 G, Unk	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Folic Acid	C		Unk	Not Reported
Triamcinolone Hexacetonide	C	Unknown	Unk	Not Reported
Triamcinolone Hexacetonide	C	Intra-articular	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	12304669	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015013797		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Impaired Work Ability; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness;	Enbrel			S	Subcutaneous	25 Milligram, 2 Times/Wk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

Nasopharyngitis; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	S	Oral	10 Milligram, Bid	Not Reported
	Xeljanz	S	Oral	5 Milliliter, Bid	Not Reported
	Xeljanz	S	Oral	10 Milliliter, Bid	Not Reported
	Xeljanz	S	Oral	Unk, Bid	Not Reported
	Xeljanz	S	Oral	10 Milliliter	Not Reported
	Xeljanz	S	Oral	5 Milliliter	Not Reported
	Celebrex	S	Oral	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Vioxx	S	Oral	Unk	Not Reported
	Vioxx	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	20 Milligram	Not Reported
	Methotrexate	S	Unknown	200 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported

	Sulfasalazine	C		Unk		Not Reported
	Wellbutrin	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	12343875	NON-EXPEDITED		OT	CA-AMGEN-CANSL2016055527		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Apo Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	12695500	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016245898		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Frustration Tolerance Decreased; Ill-Defined Disorder; Impaired Work Ability; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis; Suicidal Ideation; Swelling; Treatment Failure; Vein Disorder	Enbrel			S	Unknown	50 Mg, Unk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Actemra			S	Subcutaneous	162 Milligram		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Qwk		Not Reported
	Folic Acid			S		Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	50 Milligram, Qwk		Not Reported
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Fosamax			C		Unk		Not Reported
	Ibuprofen			C	Unknown	Unk		Not Reported
	Lisinopril			C	Unknown	Unk		Not Reported
	Vit D3			C	Unknown	Unk		Not Reported
	Alendronate Sodium			C	Unknown	Unk		Not Reported
	Mtx [Methotrexate]			C		Unk		Not Reported
	Fosavance			C		Unk		Not Reported

	Synthroid			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	13299527	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016375688		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Tuberculin Test Positive	Enbrel			S	Unknown	Unk		Pfizer
	Celecoxib			S	Oral	200 Mg, Bid		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk (Solution)		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo Celecoxib			S	Oral	200 Mg, Bid		Not Reported
	Toradol			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	7-10 Mg, Unk		Not Reported
	Tramadol			C	Unknown	100 Mg, As Necessary		Not Reported
	Prednisone			C		7-10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	13330098	EXPEDITED (15-DAY)		OT	CA-ROCHE-1693450			Female	CAN

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

Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Hypersensitivity; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Peripheral Swelling; Rash; Tendon Disorder; Therapeutic Response Decreased	Actemra	S	Unknown	Not Reported
	Bactrim	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	13917842	EXPEDITED (15-DAY)		HO, LT, OT	CA-PFIZER INC-2017371881		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Milligram		Pfizer
	Apo Sulfasalazine			S		Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S				Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Ilaris	S	Intravenous (not otherwise specified)	Unk	Not Reported
Ilaris	S	Subcutaneous	Unk	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S			Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Sodium Aurothiomalate	S			Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	14328853	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017297972		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Treatment Failure	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer

Arava	S		Unk		Not Reported
Plaquenil	S		Unk		Not Reported
Plaquenil	S	Oral	Unk		Not Reported
Actemra	S		Unk		Not Reported
Humira	S	Subcutaneous	40 Mg, Unk		Not Reported
Hydroxychloroquine Sulfate	S		Unk		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	14639970	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0752		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Overdose; Product Use Issue; Rheumatoid Arthritis; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	14817954	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2018054977		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product	Enbrel			S	Unknown	50 Milligram, Unk		Amgen

Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Enbrel	S	Subcutaneous	25 Milligram, Q2wk	Amgen
	Enbrel	S	Unknown	25 Milligram, Qwk	Amgen
	Leflunomide	S	Unknown	10 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	25 Milligram, Unk	Not Reported
	Orencia	S	Subcutaneous	250 Milligram, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Unk	Not Reported
	Salazopyrin	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
	Gold	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	20 Milligram, Bid	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Unk	Not Reported

Hydroxychloroquine	S	Unknown	300 Milligram, Unk		Not Reported
Actemra	S	Unknown	Unk		Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Qwk		Not Reported
Methotrexate	S	Unknown	20 Milligram, Qwk		Not Reported
Prednisone	C		40 Milligram, Unk		Not Reported
Prednisone	C		250 Milligram, Unk		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Milligram, Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Bifidobacterium Bifidum	C	Unknown	Unk		Not Reported
Celebrex	C	Unknown	Unk		Not Reported
Arava	C	Oral	10 Milligram, Unk		Not Reported
Loperamide	C	Unknown	Unk		Not Reported
Wellbutrin	C	Unknown	Unk		Not Reported
Pantoprazole	C	Unknown	Unk		Not Reported
Simponi	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15278631	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018110461			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Contraindicated Product Administered; Drug Intolerance; Headache; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Vomiting	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Morphine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15348973	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175923		62 YR	Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15348992	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175991		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S				Not Reported

Decreased; Treatment Failure	Enbrel		S	Subcutaneous		Not Reported
	Enbrel		S			Not Reported
	Humira		S	Subcutaneous		Not Reported
	Humira		S	Unknown		Not Reported
	Methotrexate		S	Unknown	Solution	Not Reported
	Methotrexate		S			Not Reported
	Orencia		S	Unknown		Not Reported
	Orencia		S			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Oral		Not Reported
	Desoximetasone		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15436734	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190086		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Photosensitivity Reaction; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Marijuana			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Sedimentation Rate Increased; Rheumatoid Arthritis; Stomatitis; Urticaria	Oxycodone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lyrica	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15638561	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2018-CA-978039		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial; Drug Ineffective; Fungal Infection; Off Label Use; Osteomyelitis; Systemic Infection; Systemic Mycosis	Voriconazole			S	Unknown			Teva
	Voriconazole			S	Oral			Teva
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Prednisone			S	Unknown	40 Milligram Daily;		Actavis
	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Amphotericin B			S	Unknown			Not Reported
	Amphotericin B			S	Intravenous (not otherwise specified)	200 Milligram Daily;		Not Reported
	Amphotericin B			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15683328	EXPEDITED (15-DAY)		HO, LT, OT	CA-CELLTRION INC.-2018CA024265			Unknown	CAN

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

Adrenal Insufficiency; Antibody Test Positive;	Infliximab Pfizer (Unknown)	S	Intravenous (not otherwise specified)	3 Mg/Kg, Weekly (1 Every 1 Week)	Not Reported
Arthralgia; Arthritis; Arthritis; Arthropathy;	Infliximab Pfizer (Unknown)	S	Intravenous (not otherwise specified)	5 Mg/Dose, Unk;	Not Reported
Bone Density Decreased; Bone Density Increased;	Infliximab Pfizer (Unknown)	S	Intravenous (not otherwise specified)	3 Mg/Kg, Cyclic (Once Every 6 Weeks)	Not Reported
C-Reactive Protein Abnormal; C-Reactive Protein Increased;	Infliximab Pfizer (Unknown)	S	Unknown	Unk	Not Reported
Condition Aggravated;	Infliximab Pfizer (Unknown)	S	Intravenous (not otherwise specified)	3 Mg, Weekly (1 Every 1 Week(S))	Not Reported
Condition Aggravated; Contraindicated Product Administered; Diarrhoea;	Infliximab Pfizer (Unknown)	S	Unknown	3 Mg, Weekly	Not Reported
Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use Issue; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid	Infliximab Pfizer (Unknown)	S	Unknown	5 Mg, Unk	Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg, Weekly	Not Reported
	Enbrel	S	Subcutaneous	25 Mg, 2x/Week	Not Reported
	Enbrel	S	Subcutaneous	25 Mg, Unk	Not Reported
	Enbrel	S	Subcutaneous	25 Mg	Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg, 1x/Day	Not Reported
	Enbrel	S	Subcutaneous	25 Mg, Weekly	Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg, 4times/Wk	Not Reported
	Enbrel	S	Unknown	25 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	1.5 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	12.5 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	4 Dosage Form, Qwk	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, Bid	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Mg/M2, Weekly	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Mg/M2, Weekly	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S		15 Mg, 2x/Week	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Milligram/Sq. Meter, Q2wk	Not Reported

Arthritis; Septic Shock; Short Stature; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Methotrexate Sodium	S	Subcutaneous	15 Milligram/Sq. Meter 12 Every 2 Weeks	Not Reported
	Methotrexate Sodium	S		Unk	Not Reported
	Methotrexate Sodium	S	Unknown	1 Dosage Form, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Milligram/Sq. Meter	Not Reported
	Sulfasalazine	S	Oral	250 Mg, Qd(1 Every 24 Hour(S))	Not Reported
	Sulfasalazine	S	Unknown	250 Mg, 1x/Day	Not Reported
	Sulfasalazine	S	Oral	1 Dosage Form, Qd	Not Reported
	Triamcinolone	S	Unknown	Unk	Not Reported
	Triamcinolone	S	Unknown	Unk	Not Reported
	Triamcinolone	S	Unknown	Unk	Not Reported
	Infliximab	S	Unknown	3 Mg, Weekly,Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	1 Dosage Form, Qwk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Unk	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Unk	Not Reported
	Triamcinolone Acetonide	S	Unknown	Unk	Not Reported
	Triamcinolone Acetonide	S	Oral	5 Milligram, Qd	Not Reported
	Triamcinolone Acetonide	S		Unk	Not Reported
	Hydroxychloroquine	S	Oral	5 Mg/Kg, 1x/Day (Daily)(1 Every 24 Hour(S))	Not Reported
	Hydroxychloroquine	S	Oral	5 Mg/Kg,	Not Reported
	Hydroxychloroquine	S	Oral	Unk Unk, Qd (5.0)	Not Reported
	Hydroxychloroquine	S	Oral	1 Dosage Form, Qd	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported
	Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported
	Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported

Prednisone	S	Oral	3 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	1.3 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	5 Mg, 2x/Week	Not Reported
Prednisone	S	Oral	3 Mg, 2x/Day	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	2 Dosage Form, Qd	Not Reported
Prednisone	S	Oral	3 Milligram	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Immunoglobulin (Immunoglobulin Human Normal)	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Immunoglobulin (Immunoglobulin Human Normal)	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Anakinra	S	Subcutaneous	50 Mg, 1x/Day (Daily) (1 Every 24 Hour(S)),	Not Reported
Anakinra	S	Unknown	50 Mg, Weekly	Not Reported
Anakinra	S	Subcutaneous	Unk	Not Reported
Anakinra	S	Unknown	50 Mg, 1x/Day Qd	Not Reported
Anakinra	S	Subcutaneous	1 Dosage Form, Qd	Not Reported
Abatacept	S	Intravenous (not otherwise specified)	250 Mg, Monthly	Not Reported
Abatacept	S		250 Mg, Qmo	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Cyclic (2 Every 1 Week(S)),	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Milligram, Unk	Not Reported
Triamcinolone Hexacetonide	S	Unknown	Unk	Not Reported
Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	3 Mg/Kg, Weekly	Not Reported

Orencia	S	Intravenous (not otherwise specified)	250 Mg, Monthly (1 Every 1 Month (S)	Not Reported
Orencia	S		250 Mg, Monthly Inhalation	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Mg, Unk	Not Reported
Orencia	S	Unknown	250 Mg, Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	1 Dosage Form, Qmo	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Weekly (1 Every 1 Week)	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, 2x/Week	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Unk	Not Reported
Actemra	S	Unknown	280 Mg, Cyclical	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, 1x/Day Qd	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Qwk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Q2wk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Kineret	S	Subcutaneous	50 Mg, 1 Every 1 Day	Not Reported
Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
Apo-Naproxen	S	Unknown	Unk	Not Reported
Apo-Naproxen	S		Unk	Not Reported
Apo-Prednisone	S	Oral	3 Mg, 2x/Day(2 Every 1 Day(S))	Not Reported

	Apo-Prednisone	S	Oral	5 Mg, 2x/Day(2 Every 1 Day(S))	Not Reported
	Apo-Prednisone	S	Oral	5 Milligram, 2 Times/Wk,	Not Reported
	Apo Triamcinolone Aq	S	Unknown	Unk	Not Reported
	Apo Triamcinolone Aq	S	Intra-articular	Unk	Not Reported
	Gammagard	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
	Gammagard	S		Unk	Not Reported
	Apo-Hydroxyquine	S	Oral	5 Mg, 1x/Day	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Mg, 1x/Day	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Mg, 1x/Day	Not Reported
	Gamastan	S	Intramuscular	70 G, Unk	Not Reported
	Naproxen Sodium	S	Unknown	Unk	Not Reported
	Folic Acid	C		Unk	Not Reported
	Triamcinolone Hexacetonide	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15710539	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018303849		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	50 Mg, Qwk		Unknown
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	300 Milligram, Qd		Pfizer
	Sulfasalazine			S	Unknown	500 Milligram		Pfizer
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

Apo Leflunomida	S	Unknown	20 Milligram		Not Reported
Apo Leflunomida	S	Unknown	Unk		Not Reported
Actemra	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd		Not Reported
Calcium	C	Unknown	Unk		Not Reported
Magnesium	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported
Mtx	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15719053	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016245381		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Headache; Hypertension; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Unk		Pfizer
	Enbrel			S	Unknown	50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	17.5 Mg, Unk		Unknown
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day, (Bid)		Pfizer
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S		0.8 Mg/Kg, Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Kineret			S	Subcutaneous	100 Mg, Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Oral	20 Mg, 1x/Day, (Qd)		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported

Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Unknown	40 Mg, Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Cyclic, (Q2wk)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S		Unk	Not Reported
Plaquenil	S	Unknown	300 Mg, Daily ((200mg:1 And A Half Pill), Qd)	Not Reported
Plaquenil	S	Oral	300 Mg, 1x/Day, Qd	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S		Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1 G, Cyclic: On Day 0 And Day 15	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S		1 G, Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S		Unk	Not Reported
Gold	S		Unk	Not Reported
Anakinra	S	Subcutaneous	100 Mg, Unk	Not Reported
Anakinra	S		Unk	Not Reported
Apo-Hydroxyquine	S	Oral	20 Mg, Unk, (Every Hour)	Not Reported
Apo-Hydroxyquine	S		20 Mg, Daily, (Every Hour)	Not Reported
Actonel	S	Oral	35 Mg, Weekly, Qwk	Not Reported

Leflunomide	S	Oral	20 Mg, 1x/Day, Qd	Not Reported
Apo-Leflunomide	S	Oral	20 Mg, Cyclic, Qh	Not Reported
Apo-Leflunomide	S		20 Mg, Daily (Qd (1 Every 24 Hour(S))	Not Reported
Apo-Leflunomide	S		Unk, 1x/Day	Not Reported
Hydroxychloroquine Sulfate	S		Unk, 1x/Day, Once Every 24 Hours	Not Reported
Risedronate	S		35 Mg, Weekly	Not Reported
Hydroxychloroquine	S		300 Mg, 1x/Day, Qd	Not Reported
Hydroxychloroquine	S		300 Mg, 1x/Day, Qd	Not Reported
Hydroxychloroquine	S		Unk	Not Reported
Hydroxychloroquine	S		Unk Unk, Qd	Not Reported
Hydroxychloroquine	S		300 Mg, Unk	Not Reported
Risedronate	C		35 Mg, Weekly, Qwk	Not Reported
Hydroxychloroquine Sulfate	C		300 Mg, Cyclic, Qh	Not Reported
Hydroxychloroquine Sulfate	C		Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	200 Mg, 2x/Day, Bid	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk, Weekly, Qwk	Not Reported
Prednisone	C		10 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15867790	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019002236			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S		Unk		Not Reported
	Fosamax			S		Unk		Not Reported

Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Not Reported
	Methotrexate	S		Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S		Unk	Not Reported
	Prednisone	S		Unk	Not Reported
	Reactine (Cetirizine Hydrochloride)	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Cetirizine Hydrochloride	S		10 Mg	Not Reported
	Cortisone Acetate	S		Unk	Not Reported
	Plaquenil	S			Not Reported
	Pseudoephedrine Hydrochloride	S			Not Reported
	Diclofenac Sodium	S		Unk	Not Reported
	Sulfasalazine	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	16092462	EXPEDITED (15-DAY)		OT	PHHY2019CA057177			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Synovitis	Cosentyx			S	Unknown			Novartis
	Methotrexate			S	Unknown	Unk Unk, Unknown		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk Unk, Unknown		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unknown		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unknown		Not Reported

Otezla	S	Oral	Unk Unk, Unknown		Not Reported
Plaquenil	S	Unknown	Unk Unk, Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk Unk, Unknown		Not Reported
Simponi	S	Subcutaneous	Unk Unk, Unknown		Not Reported
Stelara	S	Subcutaneous	Unk Unk, Unknown		Not Reported
Sulfasalazine	S	Unknown	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	16454389	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019134150			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Enbrel			S	Unknown	Unk Unk, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk Unk, Qwk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Bid		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	16831220	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3552		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Circumstance Or Information Capable Of Leading To Medication Error; Condition Aggravated; Intervertebral Discitis; Pyrexia; Synovitis; Transaminases Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Apo-Sulfasalazine			S	Unknown	Strength: 500 Mg		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	16891747	EXPEDITED (15-DAY)		HO, LT, OT	CA-SAMSUNG BIOEPIS-SB-2019-28949		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use Issue; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Adalimumab			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported

Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Humira	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Naproxen	S	Unknown	Unknown	Not Reported
	Naproxen	S			Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S			Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported

Triamcinolone	S	Unknown			Not Reported
Triamcinolone	S	Subcutaneous			Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unknown		Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unknown		Not Reported
Triamcinolone Acetonide	S	Unknown	Unknown		Not Reported
Triamcinolone Acetonide	S				Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Orencia	S	Unknown			Not Reported
Orencia	S	Unknown			Not Reported
Triamcinolone Hexacetonide	S	Unknown	Unknown		Not Reported
Naproxen Sodium	S	Unknown	Unknown		Not Reported
Folic Acid	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	16912193	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-201910001021			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malignant Neoplasm Of Conjunctiva	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Unk, Qd		Concordia
	Mizoribine			C	Unknown	Unk		Not Reported
	Tacrolimus Monohydrate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17030148	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201911001623			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cardiac Disorder; Pulmonary Oedema	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	40 Mg, 1 In 2 Wk (40mg/0.4ml(40 Milligram, Solution For Injection In Pre-Filled Pen)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17273061	EXPEDITED (15-DAY)		DE, HO, OT	US-PFIZER INC-2020016994		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suspected Suicide	Clindamycin Hcl			S	Oral	Unk		Pfizer
	Esomeprazole Magnesium			S	Oral	Unk		Unknown
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Cyclobenzaprine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17274911	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP005784		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Doxycycline			S	Unknown	50 Mg, Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown			Apotex
	Abatacept			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	4 Df, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	50 Mg, Q.M.T.		Not Reported
	Tylenol /00020001/			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Sulfasalazine	C	Unknown	Unk	Not Reported
	Tylenol /00020001/	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Tylenol Arthritis Pain	C	Unknown	Unk, Prn	Not Reported
	Prednisone	C	Unknown	24 Mg, Qd	Not Reported
	Prednisone	C	Unknown	23 Mg, Qd	Not Reported
	Prednisone	C	Unknown	25 Mg, Qd	Not Reported
	Prednisone	C	Unknown	10 Mg, Qd	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364055	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531428		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported

Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Diclofenac	C	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364072	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2537099			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported

	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported
	Ilaris	S	Unknown	Single-Use Vial	Not Reported
	Ilaris	S	Subcutaneous		Not Reported
	Ilaris	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364135	EXPEDITED (15-DAY)		OT	CA-ROCHE-2534200		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Hepatotoxicity; Treatment Failure	Tocilizumab			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364139	EXPEDITED (15-DAY)		HO	CA-ROCHE-2534304		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Cyst; Deafness Neurosensory; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celecoxib			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Aclasta			C				Not Reported
	Actonel			C				Not Reported
	Ergocalciferol			C				Not Reported
	Esomeprazole			C				Not Reported
	Ferrous Gluconate			C				Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]			C				Not Reported
	Loperamide			C				Not Reported
	Nasonex			C				Not Reported
	Pantoprazole Magnesium			C				Not Reported
	Prednisone			C				Not Reported
	Trazodone			C				Not Reported
	Tylenol			C				Not Reported
	Oxycodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364143	EXPEDITED (15-DAY)		HO	CA-ROCHE-2534269			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous	100 Mg Per Syringe Single Use		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown			Not Reported
	Triamcinolone Hexacetonide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364184	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533950		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased; Blood Magnesium Increased; Blood Potassium Increased;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported

Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Enbrel	S	Unknown		Not Reported
	Fentanyl	S	Unknown		Not Reported
	Gabapentin	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Nortriptyline	S	Oral		Not Reported
	Orencia	S	Vaginal		Not Reported
	Oxycontin	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Aclasta	C	Intravenous (not otherwise specified)		Not Reported
	Actonel	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Esomeprazole Magnesium Trihydrate	C			Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown		Not Reported
	Loperamide	C			Not Reported
	Nasonex	C	Unknown	Metered Dose	Not Reported
	Oxycodone Terephthalate	C	Unknown		Not Reported
	Pantoprazole Magnesium	C			Not Reported
	Perphenazine	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Trazodone	C			Not Reported
	Tylenol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364199	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533938		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous	100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Other			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364233	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533762			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364361	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530616			Female	CAN

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

	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364637	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0600			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Tenosynovitis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Leucovorin Calcium			S	Oral			Not Reported
	Cosentyx			S	Oral			Not Reported
	Diclofenac			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Meloxicam			S	Oral			Not Reported
	Otezla			S	Unknown			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Pantoprazole Magnesium			S	Unknown			Not Reported
	Synthroid			S	Unknown			Not Reported
	Diltiazem Hydrochloride			C	Unknown			Not Reported
	Fluticasone Propionate			C	Unknown			Not Reported
	Mar-Pantoprazole			C	Unknown			Not Reported
	Mometasone Furoate			C	Unknown			Not Reported
	Premarin			C	Unknown			Not Reported
	Salbutamol Sulfate			C	Unknown			Not Reported

	Tramadol Hydrochloride		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364672	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0601		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365137	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531639			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not			Not Reported

				otherwise specified)	
	Methotrexate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365159	NON-EXPEDITED			NVSC2020US027808			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Trametinib			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365204	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0625			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365355	EXPEDITED (15-DAY)		LT	CA-ROCHE-2537118			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Ilaris			S	Unknown			Not Reported
	Ilaris			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365404	EXPEDITED (15-DAY)		OT	CA-ROCHE-2532002			Female	CAN

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

Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Oral	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365439	EXPEDITED (15-DAY)		LT	CA-ROCHE-2537126			Male	CAN

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

Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra	S	Unknown	Not Reported
	Actemra	S		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S		Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Apo-Leflunomide	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Ilaris	S	Unknown	Not Reported
	Ilaris	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365468	NON-EXPEDITED		HO, OT	US-APOTEX-2020AP007164		11 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastroenteritis	Mycophenolate Mofetil			S	Unknown	Unk		Novartis

Cryptosporidial; Neutropenia	Rituximab		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365620	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024416		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Parenteral	25 Mg, Qw		Not Reported
	Methotrexate			S	Oral	22 Mg, Qw		Not Reported
	Sulfasalazine			S				Not Reported
	Adalimumab			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tocilizumab			C				Not Reported
	Prednisone			C		6 Mg, Bid		Not Reported
	Minocycline			C				Not Reported
	Penicillamine			C				Not Reported
	Ciclosporin			C				Not Reported
	Azathioprine			C		Unk Unk, Qd		Not Reported
	Actemra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365621	EXPEDITED (15-DAY)		DS, HO, OT	CA-SA-2020SA023724			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Rheumatoid Arthritis; Weight Increased	Hydroxychloroquine Sulfate			S				Sanofi
	Paracetamol			S				Not Reported
	Arava			S				Sanofi
	Sodium Aurothiomalate			S				Not Reported
	Indometacin			S				Not Reported
	Methotrexate			S				Not Reported
	Morphine Sulfate			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S		12.5 Mg, Qd		Not Reported
	Sulfasalazine			S				Not Reported
	Hydroxychloroquine			S				Sanofi
	Morphine Salt Not Specified			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365622	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024484			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Hydroxychloroquine			S	Unknown			Sanofi
	Plaquenil			S	Oral			Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral			Sanofi
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365623	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023865			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Diphenhydramine Hydrochloride			S				Sanofi
	Celecoxib			S	Oral			Not Reported
	Demerol			S				Sanofi
	Levofloxacin			S				Not Reported
	Methotrexate			S				Not Reported
	Azithromycin			S		250 Mg, Qd		Not Reported
	Cyclophosphamide			S		2000 Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral	5 Mg, 2 Every 1 Days		Not Reported
	Xeljanz			S	Oral	5 Mg, 2 Every 1 Days		Not Reported
	Xeljanz			S	Oral	5 Mg, 2 Every 1 Days		Not Reported
	Xeljanz			S	Oral	5 Mg, 2 Every 1 Days		Not Reported
	Ezetrol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365628	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023804			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S	Oral			Sanofi
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S		Unk		Not Reported
	Anakinra			S				Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365629	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023796			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Hydroxychloroquine Sulfate			S		400 Mg		Sanofi
	Methotrexate			S		20 Mg, Qd		Not Reported
	Leflunomide			S		20 Mg		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Actemra			S		8 Mg		Not Reported
	Enbrel			S				Not Reported

	Humira	S	Subcutaneous		Not Reported
	Orencia	S		750 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	C			Not Reported
	Meloxicam	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365630	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA024044			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Impaired Work Ability; Middle Insomnia; Rheumatoid Arthritis; Rheumatoid Nodule; Synovitis; White Blood Cell Count Decreased	Hydroxychloroquine			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Acetylsalicylic Acid			S		Unk		Not Reported
	Leflunomide			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Benzylpenicillin			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Acetaminophen			C		Unk		Not Reported
	Pregabalin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365632	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023787			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S				Not Reported
	Xeljanz			S				Not Reported

Tocilizumab	S				Not Reported
Simponi	S	Subcutaneous	Solution		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution		Not Reported
Orencia	S				Not Reported
Humira	S	Subcutaneous	40 Mg, Qow (Solution)		Not Reported
Enbrel	S				Not Reported
Cimzia	C	Subcutaneous	Solution		Not Reported
Prednisone	C		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365633	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023682		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S				Sanofi
	Prednisone			S				Not Reported
	Arava			S				Sanofi
	Methotrexate			S		25 Mg 4 Every 1 Week		Not Reported
	Plaquenil			S				Sanofi
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S		162 Mg, Qw		Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365634	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA023772			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disability; Drug Ineffective; Impaired Work Ability; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Qd		Sanofi
	Leflunomide			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Ibuprofen			S	Unknown			Not Reported

Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate	S	Unknown		Not Reported
	Naproxen	S	Unknown		Not Reported
	Enbrel	S	Unknown	25 Mg	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365635	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024108			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365636	EXPEDITED (15-DAY)		CA, OT	CA-SA-2020SA025775			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Hydroxychloroquine			S				Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Arava			S	Oral	10 Mg, Qd		Sanofi
	Naproxen			S	Oral	500 Mg, Bid		Not Reported
	Anakinra			S				Not Reported
	Enbrel			S		Unk Unk, Biw		Not Reported
	Humira			S	Subcutaneous			Not Reported

	Naprosyn [Naproxen]	S	Oral	500 Mg, Qd	Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S			Not Reported
	Vioxx	S			Not Reported
	Leflunomide	C		10 Mg	Not Reported
	Xeljanz	C	Oral	2 Df, Qd, 5 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365637	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023805		46 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Condition Aggravated; Condition Aggravated; Condition Aggravated; Drug Ineffective; Gait Disturbance; Herpes Zoster; Musculoskeletal Pain; Musculoskeletal Stiffness	Plaquenil			S	Unknown			Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Celebrex			C	Unknown			Not Reported
	Tramacet			C				Not Reported
	Tramadol			C		100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365638	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023795			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Plaquenil			S		200 Mg, Bid		Sanofi
	Methotrexate			S		15 Mg, Qw		Not Reported
	Arava			S		20 Mg		Sanofi
	Humira			S	Subcutaneous			Not Reported
	Actemra			S		567 Mg, Qm		Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Celebrex	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365639	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA024490		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Surgery; Synovitis	Hydroxychloroquine			S		400 Mg		Sanofi
	Leflunomide			S	Oral	Unk		Sanofi
	Naproxen			S				Not Reported
	Prednisone			S				Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S				Not Reported
	Humira			S				Not Reported
	Orencia			S				Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365641	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024414		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Hepatotoxicity; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain;	Hydroxychloroquine			S		300 Mg		Sanofi
	Arava			S		20 Mg		Sanofi
	Arava			S		10 Mg		Sanofi
	Celecoxib			S		50 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported

Peripheral Swelling; Rheumatoid Arthritis; Swelling; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Plaquenil	S		300 Mg	Sanofi
	Prednisone	S			Not Reported
	Sulfasalazine	S		2 G	Not Reported
	Enbrel	S		50 Mg, Qw	Not Reported
	Orencia	S	Subcutaneous	250 Mg	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365642	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024413		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Off Label Use; Treatment Failure	Hydroxychloroquine Sulfate			S	Unknown	5 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S				Sanofi
	Arava			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Acetaminophen			C				Not Reported
	Cyclobenzaprine			C	Unknown	10 Mg		Not Reported
	Cyclobenzaprine			C	Unknown	10 Mg		Not Reported
	Desoximetasone			C	Unknown	5 Mg, Qd		Not Reported
	Desoximetasone			C	Unknown	5 Mg, Qd		Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported
	Prednisone Acetate			C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365643	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024411		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Osteoarthritis; Synovitis	Hydroxychloroquine			S	Unknown	200 Mg		Sanofi
	Methotrexate			S	Unknown	15 Mg		Not Reported
	Leflunomide			S	Unknown	10 Mg		Sanofi
	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365644	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025808			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Plaquenil			S		200 Mg, Qd (2 Every 1 Day)		Sanofi
	Methotrexate			S		20 Mg		Not Reported
	Sulfasalazine			S		1 G, Qd (2 Every 1 Day)		Not Reported
	Leflunomide			S		20 Mg		Sanofi
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Xeljanz			C	Oral	5 Mg, Qd(2 Every 1 Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365645	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025329			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S	Oral	20 Mg, Qd		Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Folic Acid			C	Oral	5 Mg		Not Reported
	Leflunomide			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365647	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025492			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Mobility Decreased; Osteomyelitis; Rheumatoid Arthritis	Plaquenil			S		200 Mg, Qd		Sanofi
	Sulfasalazine			S		500 Mg, 4 Every 1 Days		Not Reported
	Methotrexate			S		20 Mg		Not Reported
	Leflunomide			S		20 Mg		Sanofi
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Acetaminophen			C		500 Mg		Not Reported
	Hydrocortisone Valerate			C				Not Reported
	Hydromorphone			C				Not Reported

Hydroxychloroquine Sulfate	C			Not Reported
Lyderm [Fluocinonide]	C			Not Reported
Naproxen	C		Unk	Not Reported
Naproxen	C		250 Mg, Qd	Not Reported
Prednisone	C		10 Mg, Qd	Not Reported
Sodium Aurothiomalate	C			Not Reported
Sodium Aurothiomalate	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365649	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024106		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Anaphylactic Shock; Drug Ineffective; Drug Intolerance; Nasopharyngitis; Pain; Synovitis	Hydroxychloroquine			S		400 Mg		Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Unknown	20 Mg		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365650	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023794			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Contraindicated Product Administered; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Sulfasalazine			S				Not Reported
	Methotrexate			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Lyrica			C				Not Reported

Celebrex	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365651	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025786			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Hepatotoxicity	Plaquenil			S		200 Mg, Qd		Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S				Sanofi
	Prednisone			S		6 Mg, Qd		Not Reported
	Pregabalin			S		150 Mg, Qd		Not Reported
	Sulfasalazine			S				Not Reported
	Trazodone Hydrochloride			S		25 Mg, Qd		Not Reported
	Xeljanz			S		5 Mg, Bid		Not Reported
	Imuran [Azathioprine Sodium]			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365652	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA023870			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hand Deformity; Hip Arthroplasty; Impaired Work Ability; Joint Swelling; Knee Arthroplasty; Rheumatoid Arthritis	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Arava			S	Unknown			Sanofi
	Indometacin			S	Oral	50 Mg, Qid		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	4 Mg/Kg, Q4w		Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, Q8w		Not Reported
	Indomethacin [Indometacin]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365653	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA025308			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Ulcer; Inflammation; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Plaquenil			S		400 Mg, Qd		Sanofi
	Methotrexate			S		20 Mg, Qw		Not Reported
	Leflunomide			S		Unk Unk, Qd		Sanofi
	Leflunomide			S		Unk		Sanofi
	Orencia			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365654	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023792		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Subcutaneous			Sanofi
	Arava			S	Unknown	10 Mg		Sanofi
	Actemra			S	Unknown	650 Mg, Qm		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Unknown	750 Mg, Qm		Not Reported
	Orencia			S	Subcutaneous	250 Mg		Not Reported
	Rituxan			S	Subcutaneous	1000 Mg		Not Reported
	Methotrexate			C	Unknown	20 Mg, Qw		Not Reported
	Prednisone			C		250 Mg		Not Reported
	Prednisone			C		40 Mg		Not Reported
	Sulfasalazine			C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365655	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025330			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S				Sanofi
	Plaquenil			S				Sanofi
	Doxycycline			S		50 Mg		Not Reported
	Leflunomide			S		20 Mg, Qd		Sanofi
	Enbrel			S				Not Reported
	Orencia			S				Not Reported
	Rituximab			S				Not Reported
	Methotrexate			C		25 Mg		Not Reported
	Prednisone			C		10 Mg, Qd		Not Reported
	Simponi			C	Subcutaneous	50 Mg, Qm		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365656	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023721			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; White Blood Cell Count Decreased	Hydroxychloroquine Sulfate			S				Sanofi
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Aspirine			S				Not Reported
	Leflunomide			S	Oral			Sanofi
	Methotrexate			S				Not Reported
	Procaine Benzylpenicillin			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Pregabalin			C				Not Reported
	Xeljanz			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365658	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024419		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Decreased; Weight Increased	Hydroxychloroquine Sulfate			S				Sanofi
	Plaquenil			S				Sanofi
	Amlodipine Besilate			S	Oral	5 Mg, Qd		Not Reported
	Amlodipine Besilate			S	Oral	Unk Unk, Qd		Not Reported
	Amlodipine Besilate			S	Unknown	Unk		Not Reported
	Asacol			S	Unknown	800 Mg, Tid		Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Gliclazide			S	Unknown			Not Reported
	Enbrel			S		50 Mg		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S				Not Reported
	Atacand Plus			C				Not Reported
	Bisoprolol Fumarate			C				Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported
	Diphenhydramine			C	Oral	50 Mg		Not Reported
	Ebastine			C				Not Reported
	Ferrous Gluconate			C				Not Reported
	Folic Acid			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	100 Mg		Not Reported

	Rosuvastatin Calcium	C	Not Reported
	Tylenol	C	Not Reported
	Vitamin D3	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365659	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025326			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk (Solutions)		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365660	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025296			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Off Label Use; Rash; Visual Impairment	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Sulfasalazine			S	Oral	1 G, Qd		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutanoeus		Not Reported

	Orencia	S	Unknown		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365661	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023774			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S		300 Mg, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S		200 Mg, Qw		Not Reported
	Methotrexate			S		15 Mg; Qw		Not Reported
	Methotrexate			S		20 Mg; Qw		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Actemra			S				Not Reported
	Enbrel			S		25 Mg, Qow		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Q6w		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365662	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023786		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain;	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Sanofi

Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Hydroxychloroquine		S	Oral	200 Mg, Bid	Sanofi
	Hydroxychloroquine		S	Unknown	200 Mg	Sanofi
	Prednisone		S	Oral	5 Mg, Qd	Not Reported
	Prednisone		S	Oral	5 Mg, Qd	Not Reported
	Methotrexate		S	Oral	200 Mg, Qw	Not Reported
	Methotrexate		S	Subcutaneous	200 Mg	Not Reported
	Sulfasalazine		S	Unknown	1000 Mg, Bid	Not Reported
	Leflunomide		S	Unknown	20 Mg, Qd	Sanofi
	Orencia		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous	50 Mg	Not Reported
	Humira		S	Subcutaneous	20 Mg, Qd	Not Reported
	Actemra		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365663	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025759			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Contraindicated Product Administered; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Hydroxychloroquine			S		Unk		Sanofi
	Pregabalin			S		Unk		Not Reported
	Leflunomide			S		Unk		Sanofi
	Methotrexate			S		25 Mg		Not Reported
	Mirtazapine			S		15 Mg		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365664	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023776			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S				Sanofi
	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Pregabalin			S				Not Reported
	Actemra			S				Not Reported
	Cellcept [Mycophenolate Mofetil Hydrochloride]			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S				Not Reported
	Prednisone			C				Not Reported
	Piroxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365665	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025313			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Synovitis	Plaquenil			S		Unk		Sanofi
	Arava			S		Unk		Sanofi
	Sulfasalazine			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cosentyx			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Otezla			S		Unk		Not Reported

	Remicade	S		Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365666	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA024082			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Plaquenil			S		200 Mg, Bid		Sanofi
	Leflunomide			S	Oral	10 Mg		Sanofi
	Leflunomide			S	Oral	10 Mg		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Cefazolin			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Naproxen			C		500 Mg		Not Reported
	Viread			C				Not Reported
	Xeljanz			C	Oral	5 Mg		Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365667	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA023793			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Alendronate Sodium			S	Unknown	70 Mg, Qw		Not Reported

Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Hypercalcaemia; Infusion Related Reaction; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Skin Ulcer	Codeine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Sanofi
	Methotrexate	S	Oral	10 Mg, Qw	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Actemra	S		360 Mg, Qm	Not Reported
	Enbrel	S		25 Mg	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
	Ciclosporin	C		150 Mg, Qd	Not Reported
	Prednisone	C		10 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365668	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024418			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Nausea; Off Label Use	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Sanofi
	Plaquenil Sulfate			S		400 Mg, Qd		Sanofi
	Arava			S	Unknown			Sanofi
	Methotrexate			S		25 Mg		Not Reported
	Enbrel			S	Unknown	50 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Q4w		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365669	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024036		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Transaminases Abnormal	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365680	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023790			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365681	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025307			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Drug Ineffective; Drug	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Sanofi

Intolerance; Drug Tolerance Decreased; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Migraine; Mobility Decreased; Nausea; Off Label Use; Pain In Extremity; Pneumonia; Prescribed Underdose; Pulmonary Fibrosis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Vomiting; X-Ray Abnormal	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown	10 Mg	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Arava	S	Unknown		Sanofi
	Methotrexate	S	Oral	20 Mg, Qw	Not Reported
	Leflunomide	S	Unknown		Sanofi
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1 Df	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365682	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA025328			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Arava			S		20 Mg, Qd		Sanofi
	Arava			S		10 Mg, Qd		Sanofi
	Paracetamol			S	Endocervical			Not Reported
	Plaquenil			S		200 Mg, Bid		Sanofi
	Prednisone			S	Oral	20 Ng		Not Reported
	Sulfasalazine			S	Oral	500 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported

Sulfasalazine	S	Oral	2000 Mg		Not Reported
Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
Enbrel	S		50 Mg, Qw		Not Reported
Humira	S	Subcutaneous			Not Reported
Orencia	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution		Not Reported
Simponi	S	Subcutaneous			Not Reported
Methotrexate	C		20 Mg, Qw Solution		Not Reported
Methotrexate	C		25 Mg, Qw		Not Reported
Methotrexate	C		Unk, Q4w		Not Reported
Meloxicam	C				Not Reported
Synthroid	C				Not Reported
Acetaminophen And Codeine Phosphate	C				Not Reported
Actemra	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365683	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA024415			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Nodule; Off Label Use; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus	Hydroxychloroquine			S		400 Mg		Sanofi
	Actemra			S	Unknown			Not Reported
	Leflunomide			S		10 Mg, Qd		Sanofi
	Cimzia			S	Subcutaneous			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

Erythematosus Rash; Tenosynovitis; Therapeutic Response Decreased; Tooth Disorder; Tooth Infection; Weight Decreased	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Q4w	Not Reported
	Prednisone	S	Unknown		Not Reported
	Risedronate Sodium	C		35 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17366989	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020043725		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Inflammatory Marker Increased; Pain In Extremity; Sleep Disorder Due To A General Medical Condition	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Unknown
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	400 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	400 Mg, Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17366993	EXPEDITED (15-DAY)		HO, LT	FR-ELI_LILLY_AND_COMPANY-FR202001013747		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Drug Interaction; Dyspnoea; Feeling Abnormal; Head Discomfort; Palpitations; Reading Disorder	Fluoxetine Hydrochloride			S	Unknown	1 Df, Qd, Tablet		Eli Lilly And Co
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17367375	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020048559		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17367657	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1178949			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Off Label Use	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

	Actemra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17367697	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1178528		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastric Ulcer; Malaise; Throat Cancer	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Prednisone			C	Oral	17 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17367722	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179082		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hair Follicle Tumour Benign; Off Label Use; Product Use In Unapproved Indication	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Ciclosporin			S	Unknown			Ivax

	Alendronate Sodium	S	Unknown		Actavis
	Calcium Carbonate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Barr
	Leflunomide	S			Barr
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S			Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Acetazolamide	S	Unknown		Not Reported
	Ferric Hydroxide Polymaltose Complex	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17367888	NON-EXPEDITED			US-PFIZER INC-2020044225		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Codeine Sulfate			S		Unk		Not Reported
	Yodoxin			S		Unk		Not Reported
	Augmentin			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17369219	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016056029		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen

Arava	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	5 Milligram	Not Reported
Leflunomide	S	Unknown	10 Milligram, Qd	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Q2wk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Subcutaneous	0.8 Milligram	Not Reported
Apo-Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
Methotrexate Sodium	S	Unknown	20 Mg, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	15 Milligram	Not Reported
Orencia	S	Unknown	750 Mg, Q4wk	Not Reported
Orencia	S	Unknown	750 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	5 Mg, Q8wk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	5 Milligram	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Certolizumab Pegol	C	Unknown	Unk	Not Reported

Tofacitinib	C		Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Simponi	C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	12538837	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016070695		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	400 Milligram, Qd		Not Reported
	Apo-Hydroxyquine			S	Oral	200 Milligram, Bid		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Not Reported
	Plaquenil			S	Oral	200 Milligram, Bid		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Arava			S	Oral	200 Milligram, Qd		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Oral	200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Methotrexate			C	Oral	20 Milligram, Qwk		Not Reported

	Methotrexate	C	Oral	Unk, Q2wk	Not Reported
	Methotrexate	C	Unknown	25 Milligram, Qwk	Not Reported
	Hydroxychloroquine	C	Oral	200 Milligram, Bid	Not Reported
	Hydroxychloroquine	C	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	C	Unknown	Unk	Not Reported
	Hydroxychloroquine	C	Oral	400 Milligram, Qwk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Prednisone	C	Oral	Unk	Not Reported
	Folic Acid	C	Oral	5 Milligram, Qd (6 Days Per Week)	Not Reported
	Folic Acid	C	Oral	5 Milligram	Not Reported
	Leflunomide	C	Oral	20 Milligram, Qd	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Tofacitinib Citrate	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	12705597	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1521		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Contraindicated Product Administered; Drug Ineffective; Frustration Tolerance Decreased; Ill-Defined Disorder; Impaired Work Ability; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis; Suicidal Ideation; Swelling;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported

Treatment Failure; Vein Disorder	Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Humira	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Fosamax	C	Unknown	Not Reported
	Ibuprofen	C	Unknown	Not Reported
	Lisinopril	C	Unknown	Not Reported
	Vit D3	C	Unknown	Not Reported
	Alendronate Sodium	C	Unknown	Not Reported
	Fosavance	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Mtx	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	13162393	EXPEDITED (15-DAY)		OT	CA-ROCHE-1884997		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Drug Ineffective; Fatigue; Joint Stiffness; Joint Swelling; Loss Of Personal	Rituximab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Swelling; Therapeutic Product Effect Incomplete; Therapy Non-Responder	Humira	S	Subcutaneous		Not Reported
	Leflunomide	S	Unknown	Therapy Duration: 976.0	Not Reported
	Methotrexate Sodium	S	Unknown	Therapy Duration: 9.0 Year(S)	Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Therapy Duration: 10.0 Year(S)	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Rituxan	C	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	13923554	EXPEDITED (15-DAY)		HO, LT, OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2654		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein	Methotrexate (Trade Name Unknown)			S				Not Reported
	Enbrel			S	Unknown			Not Reported

Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Product Use In Unapproved Indication; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Enbrel	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S		Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S		Not Reported
	Apo-Sulfasalazine	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Ilaris	S	Intravenous (not otherwise specified)	Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported

	Sodium Aurothiomalate	S			Not Reported
	Rituximab	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	15272092	EXPEDITED (15-DAY)		HO	US-TEVA-2018-US-943473		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Hypokalaemia; Overdose	Hydroxychloroquine			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	15400613	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186061			Female	CAN

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

	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Wellbutrin	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	15470065	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2018M1073020		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Adrenal Suppression; Blood Prolactin Increased; Cushing'S Syndrome; Drug Interaction; Galactorrhoea; Hyperprolactinaemia; Myopathy; Orthostatic Hypotension	Itraconazole			S	Oral	100 Mg, Qd		Not Reported
	Lansoprazole			S	Unknown	30 Mg, Qd		Not Reported
	Risedronate			S	Unknown	35 Mg, Unk		Not Reported
	Theophylline			S	Unknown	200 Milligram, Bid		Not Reported
	Levothyroxine			S	Unknown	75 Microgram, Qd		Not Reported
	Prednisolone			S	Unknown	7.5 Milligram, Qd		Not Reported
	Domperidone			S	Unknown	10 Milligram, Q8h,30 Mg, Qd (10 Mg, Tid)		Mylan
	Amylase/Lipase/Protease			S	Unknown	10 Milligram, Tid		Mylan
	Carbocisteine			S	Unknown	750 Milligram, Bid,750 Milligram (750mg 2 Tds)		Mylan
	Immunoglobulins Nos			S	Unknown	Unk		Mylan
	Creon			S	Unknown	10 Milligram, Q8h, (30 Milligram, Qd, 10 Mg, Tid)		Mylan
	Uniphyllin			S	Unknown	400 Milligram, Qd (200 Mg, Bid)		Mylan
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Mylan

	Propanolol /00030001/		C	Unknown	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	15500678	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018024121		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Bactrim			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	15582761	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1028			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Ulcer; Inflammation; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Pruritus; Rheumatoid Arthritis;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown	4 Times A Week		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported

Rheumatoid Factor Positive; Synovitis	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	16088849	EXPEDITED (15-DAY)		OT	PHHY2019CA056635			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	16783313	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-084437		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache;	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Gold			S	Unknown			Not Reported

Infection; Off Label Use; Pharyngeal Oedema; Rheumatoid Arthritis	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Arava	S	Unknown	20 Milligram	Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	16863631	EXPEDITED (15-DAY)		OT	PT-JNJFOC-20190929486		63 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Interstitial Lung Disease; Off Label Use; Product Use In Unapproved Indication; Pulmonary Embolism; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown	Twice 2 Weeks Apart, Cyclic (9 Cycles)		Not Reported
	Rituximab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17263011	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1001517		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster; Herpes Zoster Meningitis; Lung Neoplasm Malignant	Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Prednisolone			S	Oral	5 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	2 Dosage Form, Qd		Mylan
	Imeth /00113801/			S	Subcutaneous	10 Milligram, Qw		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17296572	EXPEDITED (15-DAY)		OT	TN-APPCO PHARMA LLC-2079273			Unknown	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Toxic Skin Eruption	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17296604	EXPEDITED (15-DAY)		DE, OT	TN-APPCO PHARMA LLC-2079274			Unknown	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Haemophagocytic Lymphohistiocytosis	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17296702	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-PFIZER INC-2020025201			Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Growth Restriction; Maternal Exposure During Pregnancy; Oligohydramnios; Premature Baby	Fluconazole			S	Transplacental	Unk		Pfizer
	Methylprednisolone			S	Transplacental	Unk		Pfizer
	Methylprednisolone			S	Transplacental	Unk		Pfizer
	Vitamin K Nos			S	Transplacental	Unk		Not Reported
	Bisulepin			S	Transplacental	Unk		Not Reported
	Nadroparine			S	Transplacental	Unk		Not Reported
	Etamsylate			S	Transplacental	Unk		Not Reported
	Privigen			S	Transplacental	Unk		Not Reported
	Flebogamma Dif			S	Transplacental	Unk		Not Reported
	Dexamethasone			S	Transplacental	Unk		Not Reported

Dexamethasone	S	Transplacental	Unk	Not Reported
Metoprolol Tartrate	S	Transplacental	Unk	Not Reported
Potassium Chloride	S	Transplacental	Unk	Not Reported
Prednisone	S	Transplacental	Unk	Not Reported
Prednisone	S	Transplacental	Unk	Not Reported
Vitamin B Complex	S	Transplacental	Unk	Not Reported
Albumin	S	Transplacental	Unk	Not Reported
Paracetamol	S	Transplacental	Unk	Not Reported
Calcium Carbonate	S	Transplacental	Unk	Not Reported
Ornidazole	S	Transplacental	Unk	Not Reported
Cefixime	S	Transplacental	Unk	Not Reported
Magnesium Lactate	S	Transplacental	Unk	Not Reported
Bisoprolol Fumarate	S	Transplacental	Unk	Not Reported
Folic Acid	S	Transplacental	Unk	Not Reported
Omeprazole	S	Transplacental	Unk	Not Reported
Cefotaxime	S	Transplacental	Unk	Not Reported
Cefotaxime	S	Transplacental	Unk	Not Reported
Hydroxychloroquine	S	Transplacental	Unk	Not Reported
Hydrocortisone	S	Transplacental	Unk	Not Reported
Vulmizolin	S	Transplacental	Unk	Not Reported
Penicillin G	S	Transplacental	Unk	Not Reported
Aminomethylbenzoic Acid	S	Transplacental	Unk	Not Reported
Vitamin D	S	Transplacental	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17363211	EXPEDITED (15-DAY)		OT	CA-ROCHE-2532630			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Intramuscular	Not Reported
	Naproxen	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Lozide [Indapamide]	C	Unknown	Not Reported
	Metformin	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Ramipril	C	Unknown	Not Reported
	Vitamin D3	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Acetylsalicylic Acid	C	Unknown	Not Reported
	Calcium	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Lantus	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370217	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179028			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Exfoliative	Azathioprine			S	Unknown			Not Reported

Rash; Fatigue; Hepatitis; Myositis; Pruritus; Pyrexia; Swelling; Urticaria; Visual Impairment	Methotrexate	S	Unknown	Barr
	Mycophenolate Mofetil	S	Unknown	Teva
	Prednisone	S	Unknown	Actavis
	Anakinra	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370247	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179012		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Asthma; Back Pain; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Hypertension; Inflammation; Pain; Septic Shock; Synovitis; Urinary Tract Infection; Urosepsis	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Salicylates Nos			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370250	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1179312			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Medication Error; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	3 Gram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370276	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-210851		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Phospholipidosis	Hydroxychloroquine			S	Unknown	400 Milligram, Daily		Sun
	Ramipril			S	Unknown	Unk		Ranbaxy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370297	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020047519		29 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Inflammation; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; X-Ray Abnormal	Methotrexate Sodium			S	Unknown	10 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Daily		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Daily		Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370526	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179211			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Diverticulitis; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus Erythematosus; Treatment	Azathioprine			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported

Failure	Orencia	S	Unknown			Not Reported
	Rituximab	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown	3000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370545	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179284			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatotoxicity; Liver Function Test Increased	Azathioprine			S	Unknown	150 Milligram Daily;		Not Reported
	Ciclosporin			S	Unknown			Actavis
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Doxycycline Hyclate			S	Unknown			Actavis
	Mercaptopurine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Methylprednisolone			S	Unknown			Actavis
	Bromocriptine			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Pamidronate Disodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tenoxicam			S	Unknown			Not Reported
	Ustekinumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370549	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179426			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use; Prescribed Underdose	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370612	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533721			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported

	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370736	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201901-000023			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chorioretinopathy	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Prednisolone			S	Oral	10 Mg, Qd		Not Reported
	Onealfa			C		Unk		Not Reported
	Onealfa			C				Not Reported
	Takepron			C		Unk		Not Reported
	Takepron			C				Not Reported
	Persantin			C		Unk		Not Reported
	Epadel T			C		Unk		Not Reported
	Bonalon			C		Unk		Not Reported
	Bonalon			C				Not Reported
	Loxonin			C		Unk		Not Reported
	Selbex			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370807	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533766		43 YR	Female	CAN

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

Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Infusion Related Reaction; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Systemic Lupus Erythematosus; Wound	Actemra	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Cortisone	S	Unknown		Not Reported
	Cortisone	S	Oral		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Cutaneous		Not Reported
	Diclofenac	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Sunconjunctival		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported

	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17371199	EXPEDITED (15-DAY)		HO, OT	CA-ASTELLAS-2018US049131		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial; Drug Ineffective; Fungal Infection; Nodule; Osteomyelitis; Rash; Systemic Infection; Systemic Mycosis	Amphotericin B, Liposome			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Astellas
	Amphotericin B, Liposome			S	Intravenous (not otherwise specified)			Astellas
	Voriconazole			S	Oral			Not Reported
	Voriconazole			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Azathioprine			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Prednisone			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Prednisone			S	Unknown	40 Mg, Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17371228	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531864		38 YR	Female	CAN

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

	Leucovorin [Folinic Acid]	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17371763	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536707			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Hepatic Enzyme Increased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Oxycodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372026	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179418			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatomyositis; Dysphagia; Gastrointestinal Disorder; Hepatitis; Muscle Disorder; Skin Disorder	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Mycophenolate Mofetil			S	Unknown	2 Gram Daily;		Teva
	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine			S	Oral	200 Milligram Daily;		Not Reported
	Myfortic			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372069	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1179359		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tacrolimus			S	Unknown	6 Dosage Forms Daily;		Not Reported
	Tacrolimus			S	Unknown	5 Dosage Forms Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Oral	17 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372076	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179282		73 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372079	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179232			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Headache; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Stomatitis; Tinnitus	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372123	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025321			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Joint Swelling; Treatment Failure	Plaquenil			S				Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw, Solution		Not Reported
	Arava			S		Tablet		Sanofi
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372133	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023785		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi

Ineffective; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Hydroxychloroquine Sulfate	S	Oral	300 Mg, Qd	Sanofi
	Hydroxychloroquine Sulfate	S	Oral	200 Mg, Qd	Sanofi
	Hydroxychloroquine Sulfate	S		Unk	Sanofi
	Arava	S	Oral	20 Mg, Qd	Sanofi
	Leflunomide	S		20 Mg, Qw	Sanofi
	Actemra	S		50 Mg, Qw	Not Reported
	Actemra	S		4.0 Mg/Kg	Not Reported
	Adalimumab	S		Unk	Not Reported
	Cimzia	S			Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Humira	S		40 Mg	Not Reported
	Orencia	S		Unk Unk, Qm	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S		1 G	Not Reported
	Rituximab	S		1 G	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S			Not Reported
	Celebrex	C			Not Reported
	Diclofenac	C			Not Reported
	Lyrica	C			Not Reported
	Methotrexate	C	Subcutaneous	20 Mg, Qw	Not Reported
	Methotrexate	C		0.8 Ml, Qw	Not Reported
	Sulfasalazine	C			Not Reported
	Tocilizumab	C	Endocervical		Not Reported
	Valsartan	C			Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Methotrexate	C	Oral	Unk Unk, Qw	Not Reported
	Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372135	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA025298			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Hydroxychloroquine Sulfate			S		400 Mg		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Leflunomide			S		Unk		Sanofi
	Naproxen			S				Not Reported
	Prednisone			S				Not Reported
	Naproxen Sodium			S	Oral			Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Form: Solution Subcutaneous		Not Reported
	Tocilizumab			S				Not Reported
	Xeljanz			S		5 Mg, 2 Every 1 Day		Not Reported
	Orencia			S				Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C		Form: Solution		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372138	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024488		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling;	Hydroxychloroquine			S		300 Mg		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg		Not Reported
	Arava			S				Sanofi

Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Sulfasalazine	S		2 Mg	Not Reported
	Celecoxib	S			Not Reported
	Leflunomide	S		10 Mg	Sanofi
	Prednisone	S			Not Reported
	Orencia	S	Subcutaneous	250 Mg	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Subcutaneous	50 Mg, 1 Every 1 Week	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372139	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025415			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S				Sanofi
	Doxycycline			S		50 Mg		Not Reported
	Leflunomide			S		20 Mg, Qd (1 Every 1 Day)		Sanofi
	Plaquenil			S		Unk		Sanofi
	Doxycycline Hyclate			S		50 Mg		Not Reported
	Enbrel			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Rituximab			S		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Simponi			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372147	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025784		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida	Hydroxychloroquine			S		300 Mg		Sanofi

Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Pyrexia; Rheumatoid Arthritis; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Arava	S				Sanofi
	Leflunomide	S	Oral	10 Mg		Sanofi
	Celecoxib	S				Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw		Not Reported
	Methotrexate	S	Subcutaneous	10 Mg		Not Reported
	Methotrexate	S	Subcutaneous	25 Mg		Not Reported
	Methotrexate	S	Subcutaneous	2.5 Mg		Not Reported
	Methotrexate	S	Oral	15 Mg, Qw		Not Reported
	Methotrexate	S		20 Mg		Not Reported
	Orencia	S	Subcutaneous			Not Reported
	Prednisone	S				Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S		2 Mg		Not Reported
	Folic Acid	C		10 Mg, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	C				Not Reported
	Simponi	C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372151	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179046			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Feeling Abnormal; Rheumatoid Arthritis; Thirst	Azathioprine			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372160	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023783			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Plaquenil			S		200 Mg, Bid		Sanofi
	Arava			S		20 Mg, Qd		Sanofi
	Sulfasalazine			S	Oral	2000 Mg		Not Reported
	Acetaminophen			S				Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S		50 Mg, Qiw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Acetaminophen;Codeine Phosphate			C				Not Reported
	Meloxicam			C				Not Reported
	Methotrexate			C		25 Mg, Qw		Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372164	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025798			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid	Hydroxychloroquine			S		400 Mg		Sanofi
	Hydroxychloroquine			S		200 Mg, 2 Every 1 Weeks		Sanofi
	Hydroxychloroquine			S		200 Mg		Sanofi
	Hydroxychloroquine			S		400 Mg		Sanofi

Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine	S		200 Mg 2 Every 1week	Sanofi
	Hydroxychloroquine	S		400 Mg, 3 Every 1 Weeks	Sanofi
	Leflunomide	S			Sanofi
	Methotrexate	S		20 Mg, Qw	Not Reported
	Leflunomide	S		Unk	Sanofi
	Sulfasalazine	S			Not Reported
	Orencia	S			Not Reported
	Enbrel	S		50 Mg, Qw	Not Reported
	Enbrel	S		50 Mg	Not Reported
	Adalimumab	S		40 Mg, 1 Every 2 Weeks	Not Reported
	Adalimumab	S	Subcutaneous	40 Mg	Not Reported
	Actemra	S	Subcutaneous	162 Mg 2 Every 1 Weeks	Not Reported
	Actemra	S		162 Mg	Not Reported
	Prednisone	C		20 Mg, Qd	Not Reported
	Xeljanz	C		5 Mg, 2 Every 1 Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372171	EXPEDITED (15-DAY)		HO	CA-ROCHE-2530390		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Vaginal			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Sulfate]				
	Sulfasalazine	S	Oral		Not Reported
	Celebrex	S	Oral		Not Reported
	Aclasta	C	Unknown		Not Reported
	Actonel	C	Unknown		Not Reported
	Ergocalciferol	C			Not Reported
	Esomeprazole	C			Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown		Not Reported
	Loperamide	C			Not Reported
	Nasonex	C			Not Reported
	Nortriptyline	C	Unknown		Not Reported
	Omega 3 [Docosahexaenoic Acid;Eicosapentaenoic Acid]	C			Not Reported
	Oxycodone Terephthalate	C			Not Reported
	Perphenazine	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Trazodone Hydrochloride	C	Unknown		Not Reported
	Tylenol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372473	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1179363		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastric Ulcer; Malaise; Throat Cancer; Thrombosis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Plaquenil			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372538	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2020M1013147		11 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17373082	EXPEDITED (15-DAY)		OT	NVSC2020US027795			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance; Malignant Neoplasm Progression; Pancreatic Carcinoma; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Trametinib			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17373885	EXPEDITED (15-DAY)		OT	TN-APPCO PHARMA LLC-2079842			Unknown	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Toxic Skin Eruption	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17374167	EXPEDITED (15-DAY)		OT	TN-APPCO PHARMA LLC-2079843			Unknown	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Toxic Skin Eruption	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17374926	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020047444		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Glucose Increased; C-Reactive Protein Increased; Chest Discomfort; Dizziness; Dyspnoea; Gastrointestinal Disorder; Influenza; Joint Swelling; Lung Disorder; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Neck Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Sarcoidosis; Sensory Loss; Therapeutic Response Decreased; Tuberculosis; Urinary Tract Infection; Vision Blurred; White Blood Cells Urine Positive	Methotrexate Sodium			S	Unknown			Pfizer
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Unk		Not Reported
	Isoniazid			S	Unknown			Not Reported
	Prednisone			S	Unknown	7.5 Mg, Unk		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	500 Mg, 1 Every 2 Weeks		Not Reported
	Acetaminophen			C	Oral	650 Mg, Unk		Not Reported
	Azathioprine			C				Not Reported
	Diphenhydramine Hydrochloride			C				Not Reported
	Folic Acid			C				Not Reported
	Glyburide			C				Not Reported
	Glyburide			C		Unk		Not Reported
	Metformin			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	100 Mg, Unk		Not Reported
	Pariet			C				Not Reported
	Ramipril			C				Not Reported
	Synthroid			C				Not Reported
	Trajenta			C				Not Reported
	Vitamin B6			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17374991	EXPEDITED (15-DAY)		OT	CA-ROCHE-2538100		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Actemra			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Solutiuon		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Therapy Duration- 730.0		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	11761994	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015241187		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Blood Creatinine Decreased; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Pain; Fatigue; Glaucoma; Haematocrit Decreased; Haemoglobin Decreased; Headache; Inflammation; Lacrimation Increased; Lymphocyte Count Increased; Monocyte Count Increased; Nasopharyngitis; Nausea; Neutrophil Count	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Cyclic: 4 Times/Week		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Milligram		Unknown
	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Hydromorphone Hydrochloride			S		Unk		Unknown
	Folic Acid			S		5 Mg, Unk		Not Reported
	Folic Acid			S		15.5 Unk		Not Reported
	Plaquenil Sulfate			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not	520 Mg, Q4wk		Not Reported

Decreased; Ocular Procedural Complication; Optic Neuritis; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis; Tinnitus; Vision Blurred; White Blood Cell Count Decreased			otherwise specified)		
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	520 Milligram	Not Reported
	Acetaminophen	S	Oral	65 Mg, Unk	Not Reported
	Acetaminophen	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	7.5 Mg, Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Dilaudid	S	Unknown	Unk	Not Reported
	Apo-Acetaminophen	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	300 Mg, Qd	Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Diphenhydramine Hydrochloride	C	Oral	50 Mg, Unk	Not Reported
	Fosavance	C		Unk Unk, Qwk	Not Reported
	Hydrocortisone	C	Intravenous (not otherwise specified)	250 Mg, Unk	Not Reported
	Hyzaar	C		12.5 Mg, Qd	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	12327018	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2013020048		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Anaemia; Arthralgia; Back Disorder; Blood Albumin Decreased; Bone Erosion; C-Reactive Protein	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported

Increased; Condition Aggravated; Contraindicated Product Administered; Diverticular Perforation; Diverticulum; Drug Ineffective; Drug Intolerance; Hand Deformity; Headache; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphadenopathy; Musculoskeletal Stiffness; Neck Mass; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Physical Disability; Rheumatoid Arthritis; Spinal Operation; Surgery; Thrombocytosis	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Naprosyn	S	Unknown	500 Milligram, Bid	Not Reported
	Orencia	S	Subcutaneous	125 Milligram, Qwk	Not Reported
	Orencia	S	Subcutaneous	125 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	125 Milligram, Qwk	Not Reported
	Apo-Methotrexate	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Abatacept	S	Subcutaneous	125 Milligram	Not Reported
	Prednisone	S	Unknown	20 Milligram A Day	Not Reported
	Prednisone	S	Unknown	2.5 Milligram, Qwk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Naprelan	C		1000 Milligram, Qd	Not Reported
	Folic Acid	C		5 Milligram, 4 Times/Wk	Not Reported
	Crestor	C		Unk	Not Reported
	Metoprolol	C		50 Milligram	Not Reported
	Gabapentin	C	Unknown	Unk	Not Reported
	Lovastatin	C	Unknown	Unk	Not Reported
	Vitamin D	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Tramadol Hydrochloride	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Naproxen	C	Unknown	500 Milligram, Bid	Not Reported

Naproxen Sodium	C	Unknown	1000 Milligram, Qd		Not Reported
Rosuvastatin Calcium	C		Unk		Not Reported
Ergocalciferol	C	Unknown	Unk		Not Reported
Rosuvastatin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	12480786	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016249481		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Incorrect Route Of Product Administration; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Off Label Use; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Rituximab			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Apo Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	12908779	EXPEDITED (15-DAY)		HO, LT, OT	CA-BAXALTA-2016BLT007821			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present; Gastroenteritis Viral; Human Anti-Human Antibody Test; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	Unk		Shire
	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	70 Gram, Unknown		Shire
	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	70 Gram, Unknown		Shire
	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	70 Gram, Unknown		Shire
	Abatacept			S	Intravenous (not otherwise specified)	200 Mg, 1x A Month		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Unknown	50 Milligram, Unknown		Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, 1x/Day:Qd		Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, 1x/Week		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	1 Dosage Form, 1x/Day:Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Unknown		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, 2x A Week		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Unknown		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, 1x A Week		Not Reported
	Enbrel			S	Subcutaneous	4 Dosage Form, 1x/Week		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral	5 Milligram, 1x/Day:Qd		Not Reported

Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting	Hydroxychloroquine	S	Oral	1 Dosage Form, 1x/Day:Qd	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3.0 Mg/Kg, Every 6 Wk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unk Unk, Every 6 Wk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Milligram, Unknown	Not Reported
	Infliximab	S	Unknown	1 Dosage Form, 1x/Day:Qd	Not Reported
	Methotrexate	S	Unknown	15 Mg/M2, 1x A Week	Not Reported
	Methotrexate	S	Subcutaneous	Unk Unk, 1x/Week	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, 1x/2wks	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	15 Mg/M2, 1x A Week	Not Reported
	Methotrexate	S	Subcutaneous	4 Dosage Form, 1x/Week	Not Reported
	Apo-Naproxen	S	Unknown	Unk	Not Reported
	Apo-Naproxen	S			Not Reported
	Apo-Prednisone	S	Oral	50 Mg, Tablet	Not Reported
	Apo-Prednisone	S	Oral	1.3 Milligram, 2x/Day:Bid	Not Reported
	Apo-Prednisone	S	Oral	5 Milligram, 2x/Day:Bid	Not Reported
	Apo-Prednisone	S	Oral	3 Milligram, 2x/Day:Bid	Not Reported
	Sulfasalazine	S	Oral	250 Mg, 1x A Day	Not Reported
	Sulfasalazine	S	Oral	1 Dosage Form	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, 2x A Week	Not Reported
	Tocilizumab	S			Not Reported

Triamcinolone	S	Unknown	Spray Metered Dose	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, 1x/Week	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, 1x/2wks	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, 1x/2wks	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Milligram, 1 Every 2 Months	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Milligram, 1x A Month	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Milligram, 1x A Month	Not Reported
Orencia	S	Intravenous (not otherwise specified)	1 Dosage Form, 1x A Month	Not Reported
Prednisone	S	Unknown	50 Milligram	Not Reported
Prednisone	S	Oral	50 Milligram, 2x/Day:Bid	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	1.3 Milligram, 2x/Day:Bid	Not Reported
Prednisone	S	Oral	1.3 Milligram, 2x/Day:Bid	Not Reported
Prednisone	S	Oral	3 Milligram, 2x/Day:Bid	Not Reported
Prednisone	S	Oral	2 Dosage Form, 1x/Day:Qd	Not Reported
Triamcinolone Acetonide	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unk	Not Reported
Triamcinolone Hexacetonide	S	Other	Unk	Not Reported

	Triamcinolone Hexacetonide	S	Unknown	Unk		Not Reported
	Folic Acid	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	13107350	EXPEDITED (15-DAY)		OT	CA-ROCHE-1877114			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Photosensitivity Reaction; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Stomatitis; Urticaria	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	For 8 Months		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Marijuana			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Oxycodone Hydrochloride			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	13224604	EXPEDITED (15-DAY)		OT	CA-ROCHE-1890646		64 YR	Female	CAN

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

Anaphylactic Shock; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Treatment Failure	Actemra	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Cyclobenzaprine	C	Unknown	Not Reported
	Cyclobenzaprine	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Prednisone Acetate	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	13231930	NON-EXPEDITED		OT	US-VALIDUS PHARMACEUTICALS LLC-US-2016VAL000196			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Hypersensitivity; Nausea; Vomiting	Lasix			S	Unknown	Unk		Validus
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	14335835	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION		49 YR	Male	CAN

PHARMA-TREX2017-2163

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	14746831	EXPEDITED (15-DAY)		HO	CA-ROCHE-2104630		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Musculoskeletal Stiffness;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported

Nail Disorder; Onychomycosis	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Arava	C	Oral	Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15227435	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016285040		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Mg, 1x/Day		Not Reported
	Arava			S	Oral	200 Mg, 1x/Day		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Apo-Hydroxyquine			S	Oral	400 Mg, 1x/Day (200 Mg 2 Tablet)		Not Reported
	Plaquenil [Hydroxychloroquine			S	Oral	200 Mg, Bid		Not Reported

Sulfate]				
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Oral	200 Milligram, Bid	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Folic Acid	C	Oral	5 Mg, 1x/Day (6 Days Per Week)	Not Reported
Folic Acid	C	Oral	5 Mg, 1x/Day	Not Reported
Prednisone	C	Oral	Unk	Not Reported
Leflunomide	C	Oral	20 Mg, 1x/Day	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Oral	200 Mg, Bid	Not Reported
Hydroxychloroquine	C	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Oral	400 Milligram, Qwk	Not Reported
Tofacitinib Citrate	C		Unk	Not Reported
Methotrexate	C	Oral	20 Milligram, Qwk	Not Reported
Methotrexate	C	Oral	Unk, Q2wk	Not Reported
Methotrexate	C	Unknown	25 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15231584	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015216365		50 YR	Female	CAN

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

Allergy To Vaccine; Condition Aggravated; Diarrhoea; Drug Ineffective; Fall; Hypersensitivity; Laryngeal Disorder; Larynx Irritation; Nausea; Product Use Issue; Product Use Issue; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Enbrel	S	Subcutaneous	Unk	Pfizer
	Methotrexate Sodium	S	Oral	Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	Unk	Unknown
	Plaquenil	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Zostavax	S	Subcutaneous	Unk (Powder For Suspension)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15286201	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20180803503		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Inflammatory Marker Increased; Pain In Extremity; Sleep Disorder Due To A General Medical Condition	Otezla			S	Oral			Celgene
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous	400 Milligram		Not Reported
	Leflunomide			S	Oral	20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	400 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15395851	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186085		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15448137	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189248		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15517815	NON-EXPEDITED		OT	CA-AMGEN-CANSL2017166286		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Subcutaneous	200 Milligram, Q2wk		Amgen
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram, Q2wk		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram, Cyclical		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported

	Humira	S	Subcutaneous	40 Milligram, Cyclical	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Methotrexate	S	Unknown	5 Milligram	Not Reported
	Leflunomide	S	Oral	5 Milligram	Not Reported
	Leflunomide	S	Oral	10 Milligram	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	5 Milligram	Not Reported
	Orencia	S	Unknown	750 Milligram	Not Reported
	Orencia	S	Unknown	750 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	5 Milligram	Not Reported
	Prednisone	C	Unknown	50 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15668198	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570721-00		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Off Label Use; Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency	Humira			S	Subcutaneous			Not Reported
	Amlodipine Besilate			S	Oral			Not Reported
	Asacol			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported

Depo-Medrol	S	Intra-articular		Not Reported
Depo-Medrol	S			Not Reported
Mesalazine	S	Oral		Not Reported
Atacand Plus	C	Oral		Not Reported
Bisoprolol Fumarate	C	Oral		Not Reported
Ferrous Gluconate	C	Oral		Not Reported
Folic Acid	C	Oral		Not Reported
Omega Allergenic Extracts	C	Intradermal		Not Reported
Tylenol	C	Unknown		Not Reported
Vitamin D3	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15675190	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573931-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Arthritis Bacterial; Device Related Sepsis; Drug Ineffective; Drug Intolerance; Gastric Disorder; Mobility Decreased; Nerve Injury; Neurological Procedural Complication; Pain; Post Procedural Complication; Procedural Complication; Rheumatoid Arthritis; Therapeutic Response Decreased	Humira			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Arava			C	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Plaquenil			C				Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15712231	EXPEDITED (15-DAY)		HO, OT	CA-ASTELLAS-2018US052428		61 YR	Female	CAN

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

Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Tacrolimus		S	Unknown		Astellas
	Tacrolimus		S	Unknown		Astellas
	Azathioprine		S	Unknown	Unk, Unknown Freq.	Not Reported
	Methotrexate		S	Unknown	Unk, Unknown Freq.	Not Reported
	Mycophenolate Mofetil		S	Unknown	Unk Unk, Unknown Freq.	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]		S	Unknown	Unk Unk, Unknown Freq.	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.	Not Reported
	Sulfasalazine		S	Unknown	Unk Unk, Unknown Freq.	Not Reported
	Gold		S	Unknown	Unk Unk, Unknown Freq.	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk Unk, Unknown Freq.	Not Reported
	Prednisone		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15912115	NON-EXPEDITED			US-ABBVIE-18K-163-2484812-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15914265	NON-EXPEDITED			US-ABBVIE-18K-163-2476752-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

	Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15915352	NON-EXPEDITED			US-ABBVIE-18K-163-2607470-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	16048932	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2018185639		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort; Arthralgia; Arthropathy; Arthropathy; Contraindicated Product Administered; Dermatitis; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Fatigue; Gallbladder Disorder; Gastric Disorder; Groin Pain; Joint Swelling; Miliaria; Miliaria; Off Label Use; Pancreatitis; Photosensitivity Reaction; Pruritus Allergic; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Unknown
	Methotrexate Sodium			S	Subcutaneous	Unk, Qwk		Unknown
	Celecoxib			S	Unknown	200 Milligram, Q12h		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk, 11:1 Mg		Pfizer
	Morphine Sulfate			S	Unknown	Unk		Unknown
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

Incomplete	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Citalopram	C	Unknown	10 Mg, 1x/Day	Not Reported
	Citalopram	C		Unk	Not Reported
	Celebrex	C		200 Mg, 2x/Day	Not Reported
	Celebrex	C		Unk	Not Reported
	Lorazepam	C		1 Mg, 1x/ Day (At Bedtime)	Not Reported
	Lorazepam	C		Unk	Not Reported
	Prednisone	C	Unknown	10 Milligram, Qd	Not Reported
	Prednisone	C		Unk	Not Reported
	Pantoloc	C		40 Mg, 2x/Week	Not Reported
	Pantoloc	C	Unknown	40 Mg, 2x/Day	Not Reported
	Pantoloc	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	16122586	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2018175541		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Milligram, Unk		Pfizer
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk		Pfizer
	Enbrel			S	Unknown	25 Mg, Qwk		Pfizer
	Salazopyrin			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	15 Milligram, Qwk		Unknown
	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	15 Mg, Weekly		Pfizer
	Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported

Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	25 Milligram	Not Reported
Orencia	S	Subcutaneous	250 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Gold	S	Subcutaneous	Unk	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	300 Mg, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	20 Mg, 2x/Day	Not Reported
Plaquenil	S	Oral	200 Milligram, Bid	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Arava	C	Oral	10 Milligram	Not Reported
Bifidobacterium Bifidum	C	Unknown	Unk	Not Reported
Celebrex	C	Unknown	Unk	Not Reported

Loperamide	C	Unknown	Unk		Not Reported
Pantoprazole	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Mg, Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	40 Milligram		Not Reported
Prednisone	C		250 Milligram		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported
Simponi	C	Unknown	Unk		Not Reported
Wellbutrin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	16133266	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0898			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	16207344	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019167550			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug	Enbrel			S	Unknown	Unk		Pfizer

Ineffective; Finger Deformity; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate Sodium		S	Unknown	Unk	Pfizer
	Methotrexate Sodium		S	Unknown	Unk	Pfizer
	Sulfasalazine		S	Unknown	Unk	Pfizer
	Actemra		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Leflunomide		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Leflunomide		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Remicade		S	Unknown	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab		S			Not Reported
	Naproxen		C		500 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	16234392	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-036882		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product Administration; Liver Function Test Increased; Off Label Use; Rash; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not	1 Gram		Not Reported

			otherwise specified)		
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Arava	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Simponi	C	Subcutaneous	50 Milligram, Qmo	Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, 2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	16722029	EXPEDITED (15-DAY)		DS, OT	CA-CELGENEUS-CAN-20190805428			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	16817760	EXPEDITED (15-DAY)			CA-VALIDUS PHARMACEUTICALS LLC-CA-2019VAL000509			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug	Plaquenil /00072603/			S	Unknown	Unk		Not Reported

Ineffective; Drug Intolerance; Hypersensitivity	Arava	C		Unk	Not Reported
	Buprenorphine	C		Unk	Not Reported
	Xarelto	C		Unk	Not Reported
	Bisoprolol	C	Unknown	Unk	Not Reported
	Lasix /00032602/	C		Unk	Not Reported
	Vitamin D /00107901/	C		Unk	Not Reported
	Vitamin B12 Nos	C		Unk	Not Reported
	Vitamin B6	C		Unk	Not Reported
	Fish Oil	C		Unk	Not Reported
	Calcium	C		Unk	Not Reported
	Magnesium	C		Unk	Not Reported
	Ramipril	C		Unk	Not Reported
	Xeljanz	C		Unk	Not Reported
	Prednisone	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17021208	EXPEDITED (15-DAY)		CA, DE, OT	FR-MYLANLABS-2019M1106907			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Bowing Of Long Bones; Congenital Osteodystrophy; Foetal Exposure During Pregnancy; Foetal Growth Restriction; Low Birth Weight Baby; Patent Ductus Arteriosus; Premature Baby; Premature Separation Of Placenta; Right-To-Left Cardiac Shunt	Esomeprazole			S	Transplacental	Maternal Dose: 20 Mg, Qd		Not Reported
	Plaquenil /00072603/			S	Transplacental	Maternal Dose: 400 Mg Qd		Mylan
	Diffu K			S	Transplacental	1 Dosage Form, Qd		Mylan
	Cortancyl			S	Transplacental	Maternal Dose:1 Df, Qd		Mylan
	Imurel /00001501/			S	Transplacental	150 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17147710	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019205773		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	8 Milligram/Kilogram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17242739	NON-EXPEDITED			NVSC2020US000828		8 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Rituximab			S	Unknown	Unk		Not Reported

	Hydroxychloroquine			S	Unknown	Unk			Novartis
	Methotrexate			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17251356	EXPEDITED (15-DAY)		OT	FR-ASTRAZENECA-2020SE00846		28 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis	Inexium			S	Oral			Astrazeneca
	Tardyferon			S	Oral			Not Reported
	Cortancyl			S	Oral			Not Reported
	Levothyrox			S	Oral	100ug/Inhal Daily		Not Reported
	Imurel			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17278596	EXPEDITED (15-DAY)		DE, HO, OT	US-ASTRAZENECA-2020SE07371		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suspected Suicide	Esomeprazole Magnesium			S	Oral	Unk		Not Reported
	Clindamycin Hcl			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Cyclobenzaprine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17316856	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020032259			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Unknown

Arthritis	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	10 Mg, Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Simponi	C	Subcutaneous	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17333011	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3253493-00		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Infection; Off Label Use; Pharyngeal Oedema; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Arava			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17373500	EXPEDITED (15-DAY)		DS	CA-ROCHE-2531906		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Joint Swelling; Limb Discomfort; Mass;	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Mobility Decreased; Pain; Peripheral Swelling	Arava	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17373594	EXPEDITED (15-DAY)		OT	CA-ROCHE-2539457		67 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17373911	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533703			Female	CAN

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

Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17374219	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533915			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Occlusive dressing technique			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Omega 3 [Docosahexaenoic Acid;Eicosapentaenoic Acid]			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Oxycontin	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Vitamin B1 [Thiamine]	S	Unknown	Not Reported
Aclasta	C	Unknown	Not Reported
Actonel	C	Unknown	Not Reported
Ascorbic Acid	C	Unknown	Not Reported
Biotin	C	Unknown	Not Reported
Cholecalciferol	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Esomeprazole	C	Unknown	Not Reported
Ferrous Fumarate	C	Unknown	Not Reported
Ferrous Gluconate	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown	Not Reported
Loperamide	C	Unknown	Not Reported
Nortriptyline	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Retinol Palmitate	C	Unknown	Not Reported
Riboflavin	C	Unknown	Not Reported
Thiamine Hydrochloride	C	Unknown	Not Reported
Trazodone	C	Unknown	Not Reported
Tylenol	C	Unknown	Not Reported
Vitamin A [Retinol]	C	Unknown	Not Reported
Vitamin B3	C	Unknown	Not Reported
Vitamin B6	C	Unknown	Not Reported
Vitamin C [Ascorbic Acid]	C	Unknown	Not Reported

	Nasonex	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17374397	EXPEDITED (15-DAY)		DE, HO	US-ALVOGEN-2020-ALVOGEN-102684		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Toxicity To Various Agents	Naproxen			S	Oral			Not Reported
	Ibuprofen			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17374779	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023720		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Joint Swelling; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Plaquenil			S		Unk		Sanofi
	Arava			S		20 Mg, Qd		Sanofi
	Methotrexate			S	Intravenous (not otherwise specified)	25 Mg, Qw		Not Reported
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	20 Mg, Qw		Not Reported
	Methotrexate			S		20 Mg Qw		Not Reported
	Actemra			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow (Solution)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17374782	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA025870			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities	Hydroxychloroquine			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S	Oral			Not Reported
	Celecoxib			S				Not Reported
	Enbrel			S				Not Reported
	Actemra			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Prednisone			C		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17375092	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540680			Female	CAN

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

	Prednisone		S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17375337	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0655		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17375889	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2537125			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17375961	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2537152			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous drip			Not Reported

Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Renal Failure	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17376135	EXPEDITED (15-DAY)		OT	CA-ROCHE-2535459			Female	CAN

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17376221	EXPEDITED (15-DAY)		OT	CA-ROCHE-2535980			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

Fosamax	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17376382	EXPEDITED (15-DAY)		OT	CA-ROCHE-2539454			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)		
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377492	NON-EXPEDITED			US-ABBVIE-19K-163-2658597-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377497	EXPEDITED (15-DAY)		HO	CN-IPCA LABORATORIES LIMITED-IPC-2020-CN-000399			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Phospholipidosis	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Ipca
	Prednisone			C	Unknown	10 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377511	NON-EXPEDITED			US-ABBVIE-19K-163-2660980-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Diarrhoea; Drug Hypersensitivity; Hepatic Function Abnormal; Psoriasis	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Glimepiride			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377526	NON-EXPEDITED			US-ABBVIE-19K-163-2658649-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377532	NON-EXPEDITED			US-ABBVIE-19K-163-2618887-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377651	NON-EXPEDITED			US-ABBVIE-19K-163-2663000-00			Unknown	USA

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

Drug Ineffective; Gastrointestinal Disorder; Rheumatoid Arthritis	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Enbrel	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377848	NON-EXPEDITED			US-ABBVIE-19K-163-2663033-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377864	NON-EXPEDITED			US-ABBVIE-19K-163-2663035-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Sinusitis; Diarrhoea; Drug Hypersensitivity; Drug Hypersensitivity; Liver Function Test Increased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hcq			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377887	NON-EXPEDITED			US-ABBVIE-19K-163-2662918-00			Unknown	USA

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

Alopecia; Diarrhoea; Drug Ineffective; Rash	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Imuran		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377912	NON-EXPEDITED			US-ABBVIE-19K-163-2628453-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Nausea; Therapeutic Product Effect Decreased; Vomiting	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377922	NON-EXPEDITED			US-ABBVIE-19K-163-2666857-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Malaise; Migraine	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377937	NON-EXPEDITED			US-ABBVIE-19K-163-2665118-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Eruption; Drug Intolerance; Necrosis; Nephrotic Syndrome; Oedema	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Penicillamine			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377951	NON-EXPEDITED			US-ABBVIE-19K-163-2636615-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377967	NON-EXPEDITED			US-ABBVIE-19K-163-2665116-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Injection Site Reaction; Pruritus; Rash; Urticaria	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377980	NON-EXPEDITED			US-ABBVIE-19K-163-2665109-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377984	NON-EXPEDITED			US-ABBVIE-19K-163-2662926-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Eye Disorder	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377988	NON-EXPEDITED			US-ABBVIE-19K-163-2667995-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378056	NON-EXPEDITED			US-ABBVIE-19K-163-2666891-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378076	NON-EXPEDITED			US-ABBVIE-19K-163-2666894-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Hand Deformity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Urticaria	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378141	NON-EXPEDITED			US-ABBVIE-19K-163-2666886-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Myalgia; Nausea; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous	12 Years		Not Reported
	Methotrexate			S	Oral	10 Years		Not Reported
	Hydroxychloroquine			S	Unknown	10 Years		Not Reported
	Sulfasalazine			S	Unknown	For 10 Years		Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378142	NON-EXPEDITED			US-ABBVIE-19K-163-2666914-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378152	NON-EXPEDITED			US-ABBVIE-19K-163-2666769-00		54 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Fatigue; Infection	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold Injections			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378188	NON-EXPEDITED			US-ABBVIE-19K-163-2666788-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Exposure During Pregnancy; Injection Site Rash	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378200	NON-EXPEDITED			US-ABBVIE-19K-163-2666879-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Gastrointestinal Disorder	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral	Prior To May 2018 For Two Years		Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378202	NON-EXPEDITED			US-ABBVIE-19K-163-2665120-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity;	Humira			S	Subcutaneous			Not Reported

Drug Hypersensitivity; Drug Intolerance	Methotrexate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378220	NON-EXPEDITED			US-ABBVIE-19K-163-2666656-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378235	NON-EXPEDITED			US-ABBVIE-19K-163-2666632-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378245	NON-EXPEDITED			US-ABBVIE-19K-163-2666741-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Product Effect Incomplete; Therapeutic Product Effect Incomplete	Leflunomide		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378252	NON-EXPEDITED			US-ABBVIE-19K-163-2668063-00			Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378260	NON-EXPEDITED			US-ABBVIE-19K-163-2666774-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378289	NON-EXPEDITED			US-ABBVIE-19K-163-2667013-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Dizziness; Drug Hypersensitivity; Drug Ineffective; Fluid Retention; Headache; Herpes Zoster; Neuropathy Peripheral;	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Stomatitis	Plaquenil		S	Unknown	Not Reported
	Xeljanz Xr		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378291	NON-EXPEDITED			US-ABBVIE-19K-163-2671146-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Colchicine			C				Not Reported
	Motrin			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378292	NON-EXPEDITED			US-ABBVIE-19K-163-2643787-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Drug Reaction; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378310	NON-EXPEDITED			US-ABBVIE-19K-163-2671152-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Treatment Failure	Humira			S	Subcutaneous			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378330	NON-EXPEDITED			US-ABBVIE-19K-163-2666975-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378352	NON-EXPEDITED			US-ABBVIE-19K-163-2666927-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378373	NON-EXPEDITED			US-ABBVIE-19K-163-2666719-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Other			Not Reported

Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Remicade		S	Unknown	Not Reported
	Cimzia		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378379	NON-EXPEDITED			US-ABBVIE-19K-163-2666659-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Malaise; Myalgia; Nausea; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Other	Usp		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378384	NON-EXPEDITED			US-ABBVIE-19K-163-2666660-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Eruption; Drug Ineffective; Drug Ineffective; Psoriasis	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378410	NON-EXPEDITED			US-ABBVIE-19K-163-2670791-00			Unknown	USA

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

Vomiting	Leflunomide		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378418	NON-EXPEDITED			US-ABBVIE-19K-163-2666952-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Disorder; Memory Impairment	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378441	NON-EXPEDITED			US-ABBVIE-19K-163-2670727-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Hypersensitivity; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378464	NON-EXPEDITED			US-ABBVIE-19K-163-2670911-00			Unknown	USA

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

	Enbrel	S	Unknown	Not Reported
	Simponi Aria	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378472	NON-EXPEDITED			US-ABBVIE-19K-163-2670898-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Mobic			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378475	NON-EXPEDITED			US-ABBVIE-19K-163-2667035-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Drug Intolerance; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378501	NON-EXPEDITED			US-ABBVIE-19K-163-2667990-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378513	NON-EXPEDITED			US-ABBVIE-19K-163-2671178-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cognitive Disorder; Contusion; Depression; Fatigue; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378529	NON-EXPEDITED			US-ABBVIE-19K-163-2646176-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Liver Function Test Increased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378540	NON-EXPEDITED			US-ABBVIE-19K-163-2670962-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Other			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378545	NON-EXPEDITED			US-ABBVIE-19K-163-2667056-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378565	NON-EXPEDITED			US-ABBVIE-19K-163-2647284-00		35 YR	Unknown	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378572	NON-EXPEDITED			US-ABBVIE-19K-163-2667992-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actamol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378573	NON-EXPEDITED			US-ABBVIE-19K-163-2667989-00			Unknown	USA

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

Drug Ineffective; Drug Ineffective; Injection Site Rash; Injection Site Rash; Pain; Pain; Swelling; Therapeutic Product Effect Decreased	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Cimzia		S	Unknown	Not Reported
	Cosentyx		S	Unknown	Not Reported
	Methotrexate		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378578	NON-EXPEDITED			US-ABBVIE-19K-163-2667062-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Primary Biliary Cholangitis; Therapeutic Product Effect Incomplete; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378602	NON-EXPEDITED			US-ABBVIE-19K-163-2671180-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378612	NON-EXPEDITED			US-ABBVIE-19K-163-2647659-00			Unknown	USA

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

Adverse Drug Reaction; Drug Ineffective	Humira		S	Subcutaneous	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Cimzia		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Methotrexate		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378635	NON-EXPEDITED			US-ABBVIE-19K-163-2671247-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction; Drug Ineffective; Drug Ineffective; Hepatic Enzyme Increased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378637	NON-EXPEDITED			US-ABBVIE-19K-163-2653591-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Infection	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378668	NON-EXPEDITED			US-ABBVIE-19K-163-2653576-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378671	NON-EXPEDITED			US-ABBVIE-19K-163-2676244-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Infection; Therapeutic Product Effect Incomplete; Upper Respiratory Tract Infection	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Other			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cefuroxime			C				Not Reported
	Flagyl			C				Not Reported
	Topiramate			C				Not Reported
	Percocet			C				Not Reported
	Darvocet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378673	NON-EXPEDITED			US-ABBVIE-19K-163-2653480-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Humira			S	Subcutaneous			Not Reported
	Doxycyclin			S	Unknown			Not Reported
	Macrobid			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Triamterene	S	Unknown	Not Reported
	Proair	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378678	NON-EXPEDITED			US-ABBVIE-19K-163-2671251-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Metotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378683	NON-EXPEDITED			US-ABBVIE-19K-163-2673925-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Rash	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Oral			Not Reported
	Hydroxychloroquine			C	Oral			Not Reported
	Hydroxychloroquine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378687	NON-EXPEDITED			US-ABBVIE-19K-163-2654903-00			Unknown	USA

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

Ineffective; Drug Ineffective; Drug Intolerance	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378701	NON-EXPEDITED			US-ABBVIE-19K-163-2654855-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378704	NON-EXPEDITED			US-ABBVIE-19K-163-2654915-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378753	NON-EXPEDITED			US-ABBVIE-19K-163-2657336-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear; Liver Function Test Abnormal; Malaise; Skin	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

Toxicity	Plaquenil		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378764	NON-EXPEDITED			US-ABBVIE-19K-163-2654916-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378772	NON-EXPEDITED			US-ABBVIE-19K-163-2657293-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378776	NON-EXPEDITED			US-ABBVIE-19K-163-2657324-00			Unknown	USA

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

	Xeljanz	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378833	NON-EXPEDITED			US-ABBVIE-19K-163-2657214-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Disorder; Injection Site Reaction; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378852	NON-EXPEDITED			US-ABBVIE-19K-163-2653583-00			Unknown	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378864	NON-EXPEDITED			US-ABBVIE-19K-163-2653595-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Eruption; Drug Ineffective; Liver Function Test Increased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Enbrel			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378872	NON-EXPEDITED			US-ABBVIE-19K-163-2672101-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			C				Not Reported
	Orencia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378876	NON-EXPEDITED			US-ABBVIE-19K-163-2672102-00			Unknown	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378899	NON-EXPEDITED			US-ABBVIE-19K-163-2657386-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378900	NON-EXPEDITED			US-ABBVIE-19K-163-2656772-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378907	NON-EXPEDITED			US-ABBVIE-19K-163-2659092-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378927	NON-EXPEDITED			US-ABBVIE-19K-163-2656775-00		71 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; General Symptom; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378938	NON-EXPEDITED			US-ABBVIE-19K-163-2657344-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Vectra (Valdecoxib)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378941	NON-EXPEDITED			US-ABBVIE-19K-163-2674610-00			Unknown	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378947	NON-EXPEDITED			US-ABBVIE-19K-163-2659106-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Injection Site Rash; Nausea; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi Aria			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Azathioprin			S	Unknown			Not Reported

	Leflunomide	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378952	NON-EXPEDITED			US-ABBVIE-19K-163-2674641-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Liver Function Test Increased; Tuberculin Test Positive	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378953	NON-EXPEDITED			US-ABBVIE-19K-163-2655231-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378955	NON-EXPEDITED			US-ABBVIE-19K-163-2672763-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Psoriasis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378956	NON-EXPEDITED			US-ABBVIE-19K-163-2657353-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378968	NON-EXPEDITED			US-ABBVIE-19K-163-2655234-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Azulfidine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378969	NON-EXPEDITED			US-ABBVIE-19K-163-2680610-00			Female	USA

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

	Plaquenil	S	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Xeljanz Xr	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378977	NON-EXPEDITED			US-ABBVIE-19K-163-2655240-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378978	NON-EXPEDITED			US-ABBVIE-19K-163-2672766-00		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Chills; Diverticulitis; Ear Congestion; Neuritis; Pain; Rash; Sinus Congestion	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflumide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Vitamin D			C	Unknown			Not Reported
	Fish Oil			C	Unknown			Not Reported
	Vitamin C			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378980	NON-EXPEDITED			US-ABBVIE-19K-163-2655230-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379003	NON-EXPEDITED			US-ABBVIE-19K-163-2658652-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379004	NON-EXPEDITED			US-ABBVIE-19K-163-2674609-00			Unknown	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379006	NON-EXPEDITED			US-ABBVIE-19K-163-2672139-00			Unknown	USA

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

Abdominal Distension; Bone Pain; Drug Ineffective; Drug Ineffective; Fatigue; Injection Site Reaction; Myalgia; Weight Increased	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Enbrel		S	Other	Not Reported
	Cimzia		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379009	NON-EXPEDITED			US-ABBVIE-19K-163-2680576-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379013	NON-EXPEDITED			US-ABBVIE-19K-163-2656935-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379023	NON-EXPEDITED			US-ABBVIE-19K-163-2678299-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Injection Site Reaction; Pain	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Plaquenil	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379024	NON-EXPEDITED			US-ABBVIE-19K-163-2655039-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug Ineffective; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379028	NON-EXPEDITED			US-ABBVIE-19K-163-2656934-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Headache	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azulfidine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379039	NON-EXPEDITED			US-ABBVIE-19K-163-2658600-00			Unknown	USA

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

	Plaquenil	S	Unknown		Not Reported
	Meloxicam	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379050	NON-EXPEDITED			US-ABBVIE-19K-163-2672549-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Malaise; Rash	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379051	NON-EXPEDITED			US-ABBVIE-19K-163-2656936-00			Unknown	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379054	NON-EXPEDITED			US-ABBVIE-19K-163-2680578-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz Xr			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379061	NON-EXPEDITED			US-ABBVIE-19K-163-2658650-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Liver Function Test Increased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379066	NON-EXPEDITED		OT	US-ABBVIE-19K-163-2675710-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Treatment Failure; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Other			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379091	NON-EXPEDITED			US-ABBVIE-19K-163-2680465-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Epistaxis; Paraesthesia	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379114	NON-EXPEDITED			US-ABBVIE-19K-163-2675964-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Blood Glucose Increased; Eye Disorder; Migraine; Nausea; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379119	NON-EXPEDITED			US-ABBVIE-19K-163-2680466-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379134	NON-EXPEDITED			US-ABBVIE-19K-163-2662836-00			Unknown	USA

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

Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Avara	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379154	NON-EXPEDITED			US-ABBVIE-19K-163-2680463-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Nausea; Pigmentation Disorder; Vomiting	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379158	NON-EXPEDITED			US-ABBVIE-19K-163-2680575-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz Xr			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379180	NON-EXPEDITED			US-ABBVIE-19K-163-2662835-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Exposure During Pregnancy; Rash	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Plaquenil	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379195	NON-EXPEDITED			US-ABBVIE-19K-163-2655279-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379198	NON-EXPEDITED			US-ABBVIE-19K-163-2675962-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Dmards (Disease Modifying Antirheumatic Drugs)			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379207	NON-EXPEDITED			US-ABBVIE-19K-163-2655292-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Injection Site Pruritus; Liver Function Test Increased	Humira			S	Subcutaneous	Treatment Length 2 Years		Not Reported
	Methotrexate			S	Unknown	Treatment Length 4 Years		Not Reported
	Actemra			S	Unknown	Treatment Length 3 Years		Not Reported

	Plaquenil	S	Unknown	Treatment Length 3 Years	Not Reported
	Prednisone	C		Continuing	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379212	NON-EXPEDITED			US-ABBVIE-19K-163-2662839-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Risk Factor; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379229	NON-EXPEDITED			US-ABBVIE-19K-163-2678304-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Rash; Swelling	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379230	NON-EXPEDITED			US-ABBVIE-19K-163-2662844-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz Xr			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379241	NON-EXPEDITED			US-ABBVIE-19K-163-2685718-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Therapeutic Product Effect Decreased; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379259	NON-EXPEDITED			US-ABBVIE-19K-163-2680577-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379260	NON-EXPEDITED			US-ABBVIE-19K-163-2662888-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379263	NON-EXPEDITED			US-ABBVIE-19K-163-2662915-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Muscular Weakness; Myalgia	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379274	NON-EXPEDITED			US-ABBVIE-19K-163-2672164-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Pain	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hcq			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379275	NON-EXPEDITED			US-ABBVIE-19K-163-2675877-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379287	NON-EXPEDITED			US-ABBVIE-19K-163-2685876-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Hypersensitivity; Latent Tuberculosis; Nightmare; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379303	NON-EXPEDITED			US-ABBVIE-19K-163-2660549-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379325	NON-EXPEDITED			US-ABBVIE-19K-163-2660734-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379334	NON-EXPEDITED			US-ABBVIE-19K-163-2680399-00			Unknown	USA

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

Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance	Humira		S	Subcutaneous	Not Reported
	Enbrel		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379340	NON-EXPEDITED			US-ABBVIE-19K-163-2685826-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Humira			S	Subcutaneous			Not Reported
	Zofran			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379348	NON-EXPEDITED			US-ABBVIE-19K-163-2676033-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Rheumatoid Arthritis; Synovitis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379358	NON-EXPEDITED			US-ABBVIE-19K-163-2660552-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Liver Function Test Increased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379374	NON-EXPEDITED			US-ABBVIE-19K-163-2673857-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Hepatic Function Abnormal	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379444	NON-EXPEDITED			US-ABBVIE-19K-163-2685872-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Drug Reaction; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379448	NON-EXPEDITED			US-ABBVIE-19K-163-2686454-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379475	NON-EXPEDITED			US-ABBVIE-19K-163-2686463-00			Unknown	USA

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

Contraindicated Product Administered; Contraindicated Product Administered; Rash; Therapeutic Product Effect Incomplete	Humira		S	Subcutaneous	Not Reported
	Enbrel		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Methotrexate		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379497	NON-EXPEDITED			US-ABBVIE-19K-163-2662758-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure; Vaginal Haemorrhage	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379532	NON-EXPEDITED			US-ABBVIE-19K-163-2658790-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379547	NON-EXPEDITED			US-ABBVIE-19K-163-2690386-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Humira			S	Subcutaneous			Not Reported
	Bupropion			S	Unknown			Not Reported

	Cyclosporine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Penicillin	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfa	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379562	NON-EXPEDITED			US-ABBVIE-19K-163-2687499-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Malaise; Pain	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Tramadol			S	Unknown			Not Reported
	Mobic			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379563	NON-EXPEDITED			US-ABBVIE-19K-163-2682481-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug Ineffective; Osteoporosis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379568	NON-EXPEDITED			US-ABBVIE-19K-163-2690387-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Drug Reaction; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379598	NON-EXPEDITED			US-ABBVIE-19K-163-2683928-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379608	NON-EXPEDITED			US-ABBVIE-19K-163-2687505-00			Unknown	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379610	NON-EXPEDITED			US-ABBVIE-19K-163-2690696-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Diarrhoea; Drug Hypersensitivity; Drug Hypersensitivity;	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Drug Hypersensitivity; Injection Site Reaction; Oedema Peripheral; Therapeutic Product Effect Incomplete	Simponi		S	Unknown	Not Reported
	Methotrexate		C		Not Reported
	Sulfasalazine		C		Not Reported
	Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379613	NON-EXPEDITED			US-ABBVIE-19K-163-2687654-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Oral Pain; Urticaria; Urticaria	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379622	NON-EXPEDITED			US-ABBVIE-19K-163-2687656-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Intolerance; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Other			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379626	NON-EXPEDITED			US-ABBVIE-19K-163-2690704-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity;	Humira			S	Subcutaneous			Not Reported

Drug Ineffective	Methotrexate		S	Oral	Not Reported
	Actemra		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Gold		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379628	NON-EXPEDITED			US-ABBVIE-19K-163-2690481-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Drug Hypersensitivity; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Xeljanz Xr			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379634	NON-EXPEDITED			US-ABBVIE-19K-163-2683932-00			Unknown	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379742	NON-EXPEDITED			US-ABBVIE-19K-163-2699997-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Humira			S	Subcutaneous			Not Reported
	Insulin			S	Unknown			Not Reported
	Lantus			S	Unknown			Not Reported
	Byetta			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Voltaren			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379804	NON-EXPEDITED			US-ABBVIE-19K-163-2692420-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Immunodeficiency; Infection; Malaise; Skin Lesion; Upper Respiratory Tract Infection	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379843	NON-EXPEDITED			US-ABBVIE-19K-163-2692238-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Headache; Nausea	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Matrix			C				Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379884	NON-EXPEDITED			US-ABBVIE-19K-163-2694201-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Gastrointestinal Disorder; Nausea	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379940	NON-EXPEDITED			US-ABBVIE-19K-163-2700215-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17380132	NON-EXPEDITED			US-ABBVIE-19K-163-2720959-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Injection Site Reaction; Injection Site Reaction; Pain	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17380314	NON-EXPEDITED			US-ABBVIE-19K-163-2684071-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Aleve			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17380337	NON-EXPEDITED			US-ABBVIE-19K-163-2666928-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Metotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17380339	NON-EXPEDITED			US-ABBVIE-19K-163-2685846-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17380341	NON-EXPEDITED			US-ABBVIE-19K-163-2692448-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Injection Site Reaction	Humira			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17380465	NON-EXPEDITED			US-ABBVIE-19K-163-2700189-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17380607	NON-EXPEDITED			US-ABBVIE-19K-163-2665125-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Inflammation; Liver Function Test Increased; Neutrophil Count Decreased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17381346	NON-EXPEDITED			US-ABBVIE-19K-163-2787760-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Fatigue; Myalgia; Pain	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17382125	NON-EXPEDITED			US-ABBVIE-19K-163-2828069-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Drug Intolerance; Drug Intolerance; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17383574	NON-EXPEDITED			US-ABBVIE-19K-163-2988548-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Urticaria	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Mobic			S	Unknown			Not Reported
	Naltrexone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17384445	NON-EXPEDITED			US-ABBVIE-19K-163-2884124-00			Unknown	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17384724	NON-EXPEDITED			US-ABBVIE-19P-163-2655187-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Injection Site Reaction; Therapy Non-Responder; Tremor	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17384744	NON-EXPEDITED		OT	US-ABBVIE-19K-163-2899418-00		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Myalgia; Swelling; Upper Respiratory Tract Infection	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Livalo			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17384758	NON-EXPEDITED			US-ABBVIE-19S-163-2678318-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Injection Site Reaction; Injection Site Reaction	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17384792	NON-EXPEDITED			US-ABBVIE-19S-163-2690751-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease; Drug Ineffective; Drug	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

Ineffective; Drug Ineffective	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17384797	NON-EXPEDITED			US-ABBVIE-19S-163-2690760-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17384888	NON-EXPEDITED			US-ABBVIE-19K-308-2957867-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Exercise Tolerance Decreased; Oropharyngeal Pain; Sinus Disorder; Throat Irritation	Humira			S	Subcutaneous			Not Reported
	Xeljanz Xr			S	Unknown			Not Reported
	Rosuvastatin			S	Unknown			Not Reported
	Ursodiol			S	Unknown	300 Mg		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Amlodipine			S	Unknown			Not Reported
	Lifitegrast			C		590 (Xiidra)		Not Reported
	Vitamin C			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Flaxseed Oil			C				Not Reported
	Omega 3			C				Not Reported
	Turmeric			C				Not Reported
	Biotin			C				Not Reported
	Calcium + Magnesium + Zink			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17385384	NON-EXPEDITED			US-ABBVIE-19K-163-2905899-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Barrett'S Oesophagus; Cough; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Gastric Disorder; Nausea; Nightmare; Peripheral Swelling; Pruritus; Skin Papilloma; Trigger Finger; Urinary Tract Infection	Humira			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Other			Not Reported
	Arava			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Azulfidine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Mobic			C	Oral			Not Reported
	Celebrex			C				Not Reported
	Celebrex			C				Not Reported
	Ibuprofen			C	Oral			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17386476	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020047495			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dactylitis; Dermatitis Psoriasiform; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Hypoacusis; Nausea; Psoriatic Arthropathy;	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Pfizer
	Cosentyx			S	Unknown	150 Mg, Monthly		Not Reported
	Humira			S	Unknown	400 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported
	Leflunomide			S	Unknown	10 Mg, Unk		Not Reported

Therapeutic Product Effect Incomplete; Vomiting	Plaquenil S	S	Unknown	200 Mg, 2x/Day		Not Reported
	Prednisone	S	Unknown			Not Reported
	Cymbalta	C	Oral	60 Mg, 1x/Day		Not Reported
	Esomeprazole Magnesium/Naproxen Sodium	C	Oral			Not Reported
	Tylenol [Paracetamol]	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17386479	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020047497			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Pain; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17386824	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-003377		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Maternal Exposure During	Topicort			S	Unknown	Not Specified		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Desoximetasone			S	Oral	Not Specified		Not Reported
	Diclofenac Sodium			S	Unknown	Not Specified		Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Prednisone	S	Unknown	Not Specified	Not Reported
	Prednisone	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Atasol	C	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17388975	EXPEDITED (15-DAY)		OT	CA-ROCHE-2535957			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17388990	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536717			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	11666289	EXPEDITED (15-DAY)		OT	CA-ROCHE-1648220			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 577.0 Nos		Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown	Duration:577.0		Not Reported
	Methotrexate			S	Unknown	Duration: 577.0		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 577.0 Nos		Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Therapy Duration: 577.0		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous	Duration: 577.0		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Duration: 577.0		Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown	Duration: 577.0		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Cortisone	C	Oral	Not Reported
	Desoximetasone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	12301325	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2014360295		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Carpal Tunnel Syndrome; Diarrhoea; Drug Ineffective; Fibromyalgia; Hepatic Enzyme Increased; Joint Swelling; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Rheumatoid Arthritis; Spinal Stenosis	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S				Pfizer
	Methotrexate Sodium			S		Between 17.5 Mg And 25mg, Weekly		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S	Oral	2 G, Daily		Pfizer
	Humira			S	Unknown	Unk		Not Reported
	Humira			S				Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported
	Arava			S		20 Mg, 1x/Day		Not Reported
	Arava			S				Not Reported
	Plaquenil			S		400 Mg, 1x/Day		Not Reported
	Plaquenil			S		Unk		Not Reported
	Plaquenil			S	Unknown	300 Mg, Weekly		Not Reported
	Tramacet			S		Unk		Not Reported
	Aclasta			S	Intravenous (not otherwise specified)	Unk, Single		Not Reported
	Tramadol/Acetaminophen			S	Oral	Unk		Not Reported
	Nortriptylin			C		20 Mg, 1x/Day At Bedtime (2 Tablets Per Day)		Not Reported
	Nortriptylin			C				Not Reported
	Metformin			C		5 Milligram, Qd		Not Reported

	Metformin	C		500 Milligram, Bid	Not Reported
	Lorazepam	C		1 Mg, 1x/Day Nightly	Not Reported
	Vagifem	C		Unk	Not Reported
	Lyrica	C	Oral	150 Mg, 2x/Day	Not Reported
	Premarin	C		0.625 Mg, Unk	Not Reported
	Vitamin D	C		Unk	Not Reported
	Calcium	C		Unk	Not Reported
	Depomedrol	C	Subcutaneous	40 Mg, Monthly	Not Reported
	Depomedrol	C	Subcutaneous	Unk Unk, Qmo	Not Reported
	Depomedrol	C			Not Reported
	Tylenol Arthritis	C		Unk	Not Reported
	Actonel Dr	C		35 Mg, Weekly	Not Reported
	Ergocalciferol	C		Unk	Not Reported
	Methylprednisolone Acetate	C	Intramuscular	40 Mg, 1 Every 1 Month	Not Reported
	Methylprednisolone Acetate	C	Subcutaneous	Unk, Monthly	Not Reported
	Methylprednisolone Acetate	C			Not Reported
	Nortriptyline Hydrochloride	C		20 Mg, Qd	Not Reported
	Nortriptyline	C		Unk (Tablet And Capsule)	Not Reported
	Nortriptyline	C			Not Reported
	Risedronate Sodium	C	Unknown	35 Milligram, Qwk	Not Reported
	Tylenol [Paracetamol]	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	12678829	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016108462			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported
	Neoral			S	Oral	20 Milligram		Not Reported
	Plaquenil			S	Oral	20 Milligram		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram	Not Reported
	Methotrexate Sodium	S	Subcutaneous	20 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	13271760	EXPEDITED (15-DAY)		OT	CA-ROCHE-1897736		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contraindicated Product Administered; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown	Therapy Duration 365 Days		Not Reported
	Leflunomide			S	Unknown	Therapy Duration: 3.0 Month(S)		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 4.0 Year(S)		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	Therapy Duration: 4.0 Month(S)		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported

	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	13602521	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-047783		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis; Synovitis; Throat Tightness	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Supeudol			C	Unknown	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	14235038	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021663		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Ill-Defined Disorder; Infection; Intentional	Hydroxychloroquine			S	Unknown	Unk, Qd		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Unk (Cyclical)		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	1 Df, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex

Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Leflunomide	S	Oral	20 Mg, 1 Every 1 Hour	Apotex
	Leflunomide	S	Oral	20 Mg, Unk (Cyclical)	Apotex
	Risedronate	S	Oral	35 Mg, Q.Wk.	Apotex
	Humira	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	35 Mg, Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Actonel	S	Unknown	35 Mg, Q.Wk.	Not Reported
	Plaquenil /00072602/	S	Oral	300 Mg, Qd	Not Reported
	Anakinra	S	Subcutaneous	100 Mg, Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Risedronic Acid	S	Oral	35 Mg, Q.Wk.	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 G, Unk (Cyclical)	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	10 Mg, Qd	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Risedronate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	14246628	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006309		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Operation; Eye Pain; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Acetaminophen			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Apo-Acetaminophen			S	Unknown			Apotex
	Apo-Prednisone			S	Unknown	7.5 Mg, Unk		Apotex
	Hydromorphone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	14549382	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP006552		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Muscle Spasms; Pain; Pain In Jaw; Rheumatoid Arthritis	Amitriptyline			S	Unknown	Unk		Apotex
	Diclofenac Sodium			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Naprosyn /00256201/			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Plaquenil /00072603/			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	14845152	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1364		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown	Qwk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Q2wk		Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Q2wk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Aleve	C	Unknown	Not Reported
	Bupropion	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	15389282	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-2667		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapeutic Product Effect Incomplete; Transplant Dysfunction; Transplant Rejection	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rapamune			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Neoral	S	Unknown	Not Reported
	Prograf	S	Unknown	Not Reported
	Prograf	S	Oral	Not Reported
	Prograf	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Imuran	C	Unknown	Not Reported
	Azathioprine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	15436912	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189344		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Musculoskeletal Disorder; Skin Warm	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	15439303	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189946		59 YR	Female	CAN

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

Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Asa	C	Unknown		Not Reported
	Clonazepam	C	Oral		Not Reported
	Desipramine	C	Unknown		Not Reported
	Gabapentin	C	Oral		Not Reported
	Nitroglycerin	C	Unknown		Not Reported
	Rosuvastatin Calcium	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	15454775	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-2785		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Bactrim	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	15679007	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2574090-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product Administration; Liver Function Test Increased; Rash; Rheumatoid Arthritis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C				Not Reported
	Leflunomide			C				Not Reported
	Prednisone			C				Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	15696246	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015057052		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Impaired Work Ability; Nasopharyngitis; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S	Subcutaneous	25 Milligram, 2 Times/Wk		Pfizer
	Xeljanz			S	Oral	5 Mg, Twice Daily		Pfizer
	Xeljanz			S	Oral	10 Mg, Twice Daily		Pfizer
	Xeljanz			S	Oral	5 Milliliter, Bid		Pfizer
	Xeljanz			S	Oral	10 Milliliter, Bid		Pfizer
	Xeljanz			S	Oral	Unk, Bid		Pfizer
	Xeljanz			S	Oral	10 Milliliter		Pfizer
	Xeljanz			S	Oral	5 Milliliter		Pfizer
	Celebrex			S	Oral	Unk		Pfizer
	Celebrex			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	15 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	200 Milligram, Qwk		Pfizer
	Vioxx			S	Oral	Unk		Not Reported
	Vioxx			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported

Orencia	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid		Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sulfasalazine	C		Unk		Not Reported
Wellbutrin	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	15749108	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3822		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Foot Deformity; Hand Deformity; Headache; Hypertension; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Pulmonary Fibrosis; Rheumatoid Arthritis; Rheumatoid Factor Positive	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Plaquenil	S	Unknown	200mg:1 And A Half Pill	Not Reported
Plaquenil	S	Oral		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Cyclical, On Day 0 And Day 15	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Unknown		Not Reported
Gold	S	Unknown		Not Reported
Anakinra	S	Subcutaneous		Not Reported
Anakinra	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Oral		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported

Actonel	S	Oral			Not Reported
Leflunomide	S	Unknown			Not Reported
Leflunomide	S	Oral			Not Reported
Apo-Leflunomide	S	Oral	Cyclic		Not Reported
Apo-Leflunomide	S	Unknown			Not Reported
Apo-Leflunomide	S	Unknown			Not Reported
Risedronate	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Xeljanz	S	Oral			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	16033390	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1019168			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer;	Methotrexate			S	Unknown			Barr
	Rosuvastatin Calcium			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Swelling; Treatment Failure	Apo-Azathioprine		S	Unknown		Not Reported
	Azathioprine		S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe		S	Subcutaneous		Not Reported
	Gold		S	Unknown		Not Reported
	Sodium Aurothiomalate		S	Intramuscular		Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported
	Cephalexin		C	Unknown	2000 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	16214358	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1183			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported

	Naproxen	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	16302392	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076872		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Drug Ineffective; Off Label Use; Pain In Extremity; Peripheral Swelling; Psoriasis	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	16481798	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1203		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Medication Error; Off Label Use; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Every 2 Week		Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Salazopyrin	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Gold	S	Subcutaneous	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Plaquenil	S	Oral	Not Reported
Actemra	S	Unknown	Not Reported

Arava	C	Unknown	Not Reported
Bifidobacterium Bifidum	C	Unknown	Not Reported
Celebrex	C	Unknown	Not Reported
Loperamide	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Simponi	C	Unknown	Not Reported
Wellbutrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	16535717	EXPEDITED (15-DAY)		OT	CA-ROCHE-2346125			Female	CAN

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

Humira	S	Subcutaneous	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Cetirizine	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	16820452	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3453			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Asthma; Breast Disorder; Bronchiectasis; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Fatigue; Gastrooesophageal Reflux Disease; Headache; Hypertension; Hypothyroidism; Mammoplasty; Mitral Valve Disease; Off Label Use; Pneumonia; Respiratory Disorder;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Bactrim			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Azathioprine Sodium			S	Unknown			Not Reported

Rheumatoid Arthritis;
Rheumatoid Nodule

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	16901988	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2956672-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatotoxicity; Liver Function Test Increased	Humira			S	Subcutaneous			Not Reported
	Tenoxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Bromocriptine			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Ustekinumab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Pamidronate Disodium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Mercaptopurine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	16942141	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2019M1098880		69 YR	Female	GBR

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

Anaemia; Arthropathy; Iron Deficiency; Lethargy; Myelodysplastic Syndrome; Pancytopenia; Platelet Count Decreased	Metformin		S	Unknown	Unk	Not Reported
	Humira		S	Unknown	Unk	Mylan
	Humira		S	Unknown	40 Milligram	Mylan
	Methotrexate		S	Unknown	Unk	Mylan
	Hydroxychloroquine		S	Unknown	200 Milligram, Qd	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17072593	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1140303		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Ciclosporin			S	Unknown			Ivax
	Ciclosporin			S	Oral			Ivax
	Ciclosporin			S	Oral			Ivax
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Imuran	S	Unknown	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Lyrica	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Simponi	S	Unknown	Not Reported
Piroxicam	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17164952	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019538925		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer

Humira	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Actemra	S	Unknown	8 Milligram/Kilogram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17388029	EXPEDITED (15-DAY)		HO	CA-ROCHE-2534191			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Immunoglobulins [Immunoglobulins Nos]			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Increased; Septic Shock; Synovitis; Vomiting	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17388411	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540683			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Hepatic Cirrhosis; Synovitis; Treatment Failure; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17388482	EXPEDITED (15-DAY)		OT	CA-ROCHE-2537431		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

Positive; Synovitis; Vomiting				otherwise specified)	
	Sulfasalazine		S	Unknown	Not Reported
	Anakinra		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17389020	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020050435			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Nausea; Neuropathy Peripheral	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Arava			S		20 Mg, 1x/Day		Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg, 1 Every 12 Hours		Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg, 1 Every 12 Hours		Not Reported
	Lyrica			C		Unk		Not Reported
	Meloxicam			C		Unk		Not Reported
	Xeljanz			C		5 Mg, Unk (Every 12 Hours)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17389033	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020052260			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate Sodium			S	Oral	20 Mg, Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, 1x/Day		Not Reported
	Humira			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17389049	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020050421			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Steatosis; Interstitial Lung Disease; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	1 G, 2x/Day		Pfizer
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, 2x/Day		Not Reported
	Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported
	Prednisone			S	Oral	15 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17389191	EXPEDITED (15-DAY)		DS	CA-ROCHE-2540903			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17389209	EXPEDITED (15-DAY)		OT	CA-ROCHE-2537446			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17389402	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536025		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Neutropenia; Platelet Count Decreased; Respiratory Tract Infection	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Viral; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Xeljanz		S	Oral	Not Reported
	Advil [Ibuprofen]		C	Unknown	Not Reported
	Folic Acid		C	Unknown	Not Reported
	Ketorolac		C	Unknown	Not Reported
	Methotrexate		C	Unknown	Not Reported
	Naproxen		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17389519	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536665		60 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17389826	EXPEDITED (15-DAY)		OT	NVSC2020CA030586			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Hypersensitivity; Impaired Work Ability; Pain; Rheumatoid Arthritis; Swelling; Vomiting	Methotrexate			S	Unknown	Unk		Novartis
	Ibuprofen			S	Unknown	Unk		Not Reported
	Codeine Phosphate			S	Unknown	Unk		Not Reported
	Crestor			S	Unknown	20 Mg, Qd		Not Reported
	Tylenol			S	Unknown	282 Ot		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17390361	EXPEDITED (15-DAY)		DS, OT	CA-BAUSCH-BL-2020-003369		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis;	Diclofenac			S	Ophthalmic			Bausch And Lomb
	Topicort			S	Cutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseud Oephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfathalidine	S	Oral	Not Reported
	Sulfathalidine	S	Oral	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Atasol	C		Not Reported
	Salazopyrin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17390484	EXPEDITED (15-DAY)		OT	CA-ROCHE-2535796			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown	84.0 Days		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	4.0 Years		Not Reported
	Leflunomide			S	Oral	4.0 Years		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	730.0		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17390675	EXPEDITED (15-DAY)		HO, OT	ALC2020CA001016			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain;	Phenylephrine Hydrochloride Injection Usp			S	Unknown	Not Specified		Alcon
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg, Ot (1 Every 1 Month)		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20.0 Mg		Not Reported
	Benzalkonium Chloride			S	Unknown	Unk		Not Reported
	Benzalkonium Chloride;Diphenhydramine Hydrochloride;Phenylephrine Hydr			S	Unknown			Not Reported

Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Benzalkonium Chloride;Diphenhydramine Hydrochloride;Phenylephrine Hydr	S	Unknown	Unk	Not Reported
	Boric Acid	S	Unknown		Not Reported
	Cimzia	S	Unknown		Not Reported
	Diphenhydramine Hydrochloride	S	Unknown		Not Reported
	Disodium Edetate	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	50.0 Mg, Ot (1 Every 1 Weeks)	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40.0 Mg Cyclical	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200.0 Mg (2 Every 1 Days)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	15.0 Mg 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Rho D Immune Globulin	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Sodium Borate	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Tofacitinib Citrate	S	Unknown	5.0 Mg 2 Every 1 Days	Not Reported
	Tofacitinib Citrate	S	Unknown	10.0 Unk 2 Every 1 Days	Not Reported
	Tofacitinib Citrate	S	Unknown	5.0 G 2 Every 1 Week	Not Reported
	Tofacitinib Citrate	S	Subcutaneous	5.0 Unk 2 Every 1 Days	Not Reported
	Xeljanz	C	Oral	5.0 Mg 2 Every 1 Days	Not Reported
	Ibuprofen	C	Unknown	Unk	Not Reported

Ibuprofen	C	Oral	400.0 Mg		Not Reported
Celebrex	C	Oral	400.0 Mg		Not Reported
Lipitor	C	Oral	10.0 Mg, Ot 1 Every 1 Days		Not Reported
Lipitor	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17390768	EXPEDITED (15-DAY)		OT	CA-ROCHE-2535761		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Musculoskeletal Disorder; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17390821	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0675		29 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Inflammation; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; X-Ray Abnormal	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17390834	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0681		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Glucose Increased; C-Reactive Protein Increased; Chest Discomfort; Dizziness; Dyspnoea; Gastrointestinal Disorder; Influenza; Joint Swelling; Lung Disorder; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Neck Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Sarcoidosis; Sensory Loss; Therapeutic Response Decreased; Tuberculosis; Urinary Tract Infection; Vision Blurred; White Blood Cells Urine Positive	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Isoniazid			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported
	Diphenhydramine Hydrochloride			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Glyburide			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Methylprednisolone			C	Unknown			Not Reported
	Pariet			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Trajenta			C	Unknown			Not Reported
	Vitamin B6			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17390978	EXPEDITED (15-DAY)		OT	CA-ROCHE-2535637		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rosuvastatin Calcium			S	Oral			Not Reported
	Rosuvastatin Calcium			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17391199	EXPEDITED (15-DAY)		DE, HO, LT	CA-ROCHE-2537139			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Ilaris	S	Unknown	Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17391712	EXPEDITED (15-DAY)		OT	CA-ROCHE-2538305		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatitis; Therapeutic Product Effect Decreased	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Humira	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17391716	EXPEDITED (15-DAY)		OT	NVSC2020DE026206			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby	Prednisolone			S	Transplacental	Mother Dose:5 Mg, Qd (Initially 5 Mg/D Until Gw 6+2, Then Discontinued. From Gw 23+3 Until Delivery		Novartis
	Quensyl			S	Transplacental	Mother Dose: 200 Mg, Qd		Not Reported
	Folsaeure			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17391789	EXPEDITED (15-DAY)		OT	CA-ROCHE-2538050		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rosuvastatin	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17391992	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533842			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gamastan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

	Sulfasalazine		S	Oral	Not Reported
	Triamcinolone		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17392075	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536228		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17392107	EXPEDITED (15-DAY)		OT	CA-ROCHE-2541650		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown	577.0		Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown	577.0		Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral	577.0		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	577.0		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Oral	577.0	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown	577.0	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown	577.0	Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	577.0	Not Reported
	Remicade	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Simponi	S	Subcutaneous	577.0	Not Reported
	Desoximetasone	C	Oral		Not Reported
	Desoximetasone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17392509	EXPEDITED (15-DAY)		OT	CA-ROCHE-2539797		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatitis; Therapeutic Product Effect Decreased	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17392519	EXPEDITED (15-DAY)		DS	CA-ROCHE-2540672		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Disability; Drug Ineffective; Headache; Malaise	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17392615	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536712		70 YR	Female	CAN

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

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Potassium Chloride	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17392847	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542897			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Leflunomide			C	Oral			Not Reported
	Meloxicam			C				Not Reported
	Methotrexate			C				Not Reported
	Synthroid			C				Not Reported
	Tylenol			C				Not Reported
	Codeine			C				Not Reported
	Phosphoric Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17393269	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540678		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Musculoskeletal Disorder; Skin Warm	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17444146	DIRECT	Y				46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Palpitations	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	13277559	EXPEDITED (15-DAY)		HO, OT	CA-BAXTER-2017BAX008638		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchiectasis; Disease Susceptibility; Drug Ineffective; Joint Swelling; Myocardial Infarction; Pulmonary Fibrosis; Toxicity To Various Agents; Upper Limb	Procytox (Cyclophosphamide) 2000mg/Vial			S	Unknown	Dosage Form Not Specified		Baxter
	Arava			S	Oral	Dosage Form: Tablet		Not Reported
	Cimzia			S	Subcutaneous	Dosage Form Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported

Fracture	Humira	S	Subcutaneous	Dosage Form Solution Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Dosage Form Not Specified	Not Reported
	Plaquenil	S	Oral	Dosage Form: Tablet	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Dosage Form Powder For Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Dosage Form Solution Subcutaneous	Not Reported
	Methotrexate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	15934147	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656830-00		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation; Pneumonia; Pruritus; Rheumatoid Arthritis; Urosepsis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methyl Salicylate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17392885	EXPEDITED (15-DAY)		OT	CA-ROCHE-2538062			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Hepatic Enzyme Increased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Oxycodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17392930	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542449		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Unknown			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported

	Remicade	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17392932	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542453		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17392959	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542450		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Xeljanz Xr			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17392964	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542472		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug	Actemra			S	Intravenous (not			Not Reported

Ineffective; Drug Intolerance; Fatigue; Treatment Failure			otherwise specified)	
	Rituxan	S	Endocervical	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Neoral	S	Unknown	Not Reported
	Neoral	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17392968	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540896			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Arthritis	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17393039	EXPEDITED (15-DAY)		HO	CA-ROCHE-2535807		77 YR	Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17393055	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542476		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)	
	Apo-Leflunomide	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Neoral	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17393141	EXPEDITED (15-DAY)		OT	CA-ROCHE-2535785		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Rheumatoid Arthritis; Sleep Disorder	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Minocycline	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Myochrysine	S	Unknown	Not Reported
Otezla	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Salazopyrin	S	Unknown	Not Reported
Simponi	S	Unknown	Not Reported
Sirukumab	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Ustekinumab	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Methotrexate	C	Unknown	Not Reported
Orencia	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17393173	EXPEDITED (15-DAY)		OT	CA-ROCHE-2535972		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Pulmonary Mass	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Calcium Carbonate			C				Not Reported
	Cetirizine			C				Not Reported
	Cranberry [Vaccinium Spp.]			C				Not Reported
	Prednisone			C				Not Reported
	Quinapril Hydrochloride			C				Not Reported
	Rabeprazole			C				Not Reported

	Singulair	C	Not Reported
	Olopatadine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17393176	EXPEDITED (15-DAY)		HO	CA-ROCHE-2535906		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Ulcer	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Prednisone	C		Not Reported
	Ciclosporin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17393316	EXPEDITED (15-DAY)		HO	CA-ROCHE-2536017		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17393407	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540921			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17393409	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542447		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17393411	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542467		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported

	Apo-Leflunomide	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Neoral	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2020	17393740	EXPEDITED (15-DAY)		HO	NVSC2020FR028239		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Muscular Weakness; Myalgia; Peripheral Sensorimotor Neuropathy	Doxycycline			S	Oral	200 Mg, Qd		Novartis
	Metronidazole			S	Oral	1500 Mg, Qd		Not Reported
	Atorvastatin			S	Oral	40 Mg, Qd		Not Reported
	Tavanic			S	Oral	1 Df, Qd		Not Reported
	Plaquenil			S	Oral	3 Df, Qd		Not Reported
	Lansoprazole			C	Oral	15 Mg, Qd		Not Reported
	Clopidogrel			C	Oral	75 Mg, Qd		Not Reported
	Fluconazole			C	Oral	200 Mg, Qd		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	11953789	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		37 YR	Female	CAN

BMS-2015-069962

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Asthenia; Condition Aggravated; Cough; Drug Ineffective; Fatigue; Fine Motor Skill Dysfunction; Goitre; Headache; Inflammation; Joint Swelling; Knee Arthroplasty; Lower Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Thyroid Disorder	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Methotrexate			S	Oral	15 Mg, Qwk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	3.0 Milligram, Qd		Not Reported
	Apo-Prednisone			S	Oral	50.0 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	15 Milligram, Qwk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral	15 Mg, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Oral	50 Mg, Qd		Not Reported
	Prednisone			S	Oral	3 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	8 Mg/Kg, Qmo		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

Humira	S	Subcutaneous	Unk		Not Reported
Simponi	S	Unknown	Unk		Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported
Losec [Omeprazole]	C	Unknown			Not Reported
Naprosyn [Naproxen]	C	Unknown			Not Reported
Celexa [Citalopram Hydrobromide]	C	Unknown			Not Reported
Crestor	C	Unknown			Not Reported
Ketoprofen	C	Unknown	100 Mg, Bid		Not Reported
Citalopram Hydrobromide	C	Unknown			Not Reported
Rosuvastatin Calcium	C	Unknown			Not Reported
Naproxen	C	Unknown			Not Reported
Omeprazole	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	12689721	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016400948			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	12709758	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0313		50 YR	Male	CAN

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

Anaemia; Back Disorder; Blood Albumin Decreased; Condition Aggravated; Contraindicated Product Administered; Diverticulum; Drug Ineffective; Drug Intolerance; Headache; Intestinal Perforation; Loss Of Personal Independence In Daily Activities; Lymphadenopathy; Neck Mass; Off Label Use; Rheumatoid Arthritis; Spinal Operation; Thrombocytosis	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Naprosyn	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Abatacept	S	Subcutaneous		Not Reported
	Apo-Methotrexate	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Folic Acid	C	Unknown	4 Days A Week	Not Reported
	Gabapentin	C	Unknown		Not Reported
	Lovastatin	C	Unknown		Not Reported
	Metoprolol	C	Unknown	Strength: 50 Mg	Not Reported
	Vitamin D	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Tramadol Hydrochloride	C	Unknown		Not Reported
	Crestor	C	Unknown		Not Reported
	Naprelan	C	Unknown		Not Reported

	Naproxen	C	Unknown	Not Reported
	Naproxen Sodium	C	Unknown	Not Reported
	Rosuvastatin Calcium	C	Unknown	Not Reported
	Rosuvastatin	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	12967538	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091608			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Arthralgia; Condition Aggravated; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Eye Disorder; Feeling Abnormal; Finger Deformity; Foot Deformity; Gait Disturbance; Gait Inability; Hyperhidrosis; Inflammation; Intervertebral Disc Protrusion; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Off Label Use; Osteoarthritis; Osteoporosis; Peripheral Swelling; Poor Quality Sleep; Rheumatoid Arthritis; Spinal Disorder; Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Vomiting; Wrist Deformity	Abatacept			S	Unknown	125 Milligram, Qwk		Bristol Myers Squibb
	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Prednisone			S	Unknown	5 Mg, Unk		Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Winpred			S	Unknown	5 Milligram		Not Reported
	Oxycodone Terephthalate			S	Oral			Not Reported
	Macrogol			S	Unknown			Not Reported
	Apo Prednison			S	Unknown	5 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydromorphone			S	Oral	12 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Percocet [Oxycodone Hydrochloride;Oxycodone			C	Unknown			Not Reported

Terephthalate;Paracetamol]					
Paracetamol	C	Unknown	Unk		Not Reported
Premarin	C	Unknown	Unk		Not Reported
Lax-A-Day	C	Unknown	Unk		Not Reported
Monurol	C	Unknown			Not Reported
Fosfomycin Trometamol	C	Unknown			Not Reported
Acetaminophen;Oxycodone Hydrochloride	C	Unknown			Not Reported
Premarin	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	13424028	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017013202		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Cimzia			S	Subcutaneous	Usual Dose For More Than 3 Months		Not Reported
	Enbrel			S		50 Mg, Unk		Not Reported
	Methotrexate			S		Usual Dose For More Than 3 Months		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Tofacitinib Citrate			S	Oral	5 Mg, 2x/Day (Bid)		Not Reported
	Arava			S		Unk		Not Reported
	Leflunomide			S		Usual Dose For More Than 3 Months		Not Reported
	Plaquenil			S		Usual Dose For More Than 3 Months		Not Reported
	Humira			S	Subcutaneous	Usual Dose For More Than 3 Months		Not Reported
	Actemra			S		Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Apo-Leflunomide	S	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unk	Not Reported
	Aspirin	C	Unk	Not Reported
	Synthroid	C	Unk	Not Reported
	Cymbalta	C	Unk	Not Reported
	Hydromorphone	C	Unk	Not Reported
	Penicillin	C	Unk	Not Reported
	Acetylsalicylic Acid	C		Not Reported
	Remicade	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	13610813	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1627		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Fall; Hypersensitivity; Laryngeal Disorder; Larynx Irritation; Nausea; Product Use Issue; Pruritus; Rheumatoid Arthritis; Weight Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	13840401	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091533			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Migraine; Mobility Decreased; Nausea; Off Label Use; Pain In Extremity; Pneumonia; Prescribed Underdose; Pulmonary Fibrosis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Treatment Failure; Vomiting; X-Ray Abnormal	Orencia			S	Intravenous (not otherwise specified)	1 Dosage Form		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown	10 Milligram		Not Reported
	Prednisone			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown	200 Milligram, Qd		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	14128708	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017042210			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Contraindication To Medical Treatment; Drug Ineffective; Hypersensitivity; Ovarian Disorder; Pulmonary Toxicity; Rheumatoid Arthritis; Treatment Failure	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	14308679	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016008213			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Certolizumab Pegol Ra			S	Subcutaneous	400 Mg, Ev 2 Weeks(Qow)		Not Reported
	Certolizumab Pegol Ra			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Not Reported
	Certolizumab Pegol Ra			S		Unk		Not Reported
	Arava			S		20 Mg, Once Daily (Qd)		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Milligram		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S		750 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tylenol			S		Unk		Not Reported
	Enbrel			S		50 Mg, Weekly (Qw)		Not Reported
	Enbrel			S		Unk		Not Reported

	Plaquenil	S		200 Mg, 2x/Day (Bid)	Not Reported
	Sulfasalazine	S	Oral	2000 Mg, Unk For 6 Months	Not Reported
	Acetaminophen	S		325 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S		200 Mg, 2x/Day (Bid)	Not Reported
	Methotrexate	S		25 Mg/ Ml, Weekly (Qw)	Not Reported
	Methotrexate	S		20 Milligram, Weekly (Qw)	Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day (Bid)	Not Reported
	Synthroid	C		Unk	Not Reported
	Leflunomide	C		Unk	Not Reported
	Meloxicam	C		Unk, Weekly (Qw)	Not Reported
	Tylenol With Codein #3	C			Not Reported
	Acetaminophen W/Codeine	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	14704614	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018012672		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Depression; Drug Ineffective; Drug Intolerance; Finger Deformity; Headache; Hyperhidrosis; Joint Swelling; Limb Discomfort; Nausea; Night Sweats; Off Label Use; Osteoarthritis; Palpitations; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Not Reported
	Arava			S	Oral	20 Mg, Once Daily (Qd)		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Ev 4 Weeks		Not Reported
	Plaquenil			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral	25 Mg, Weekly (Qw)		Not Reported
	Methotrexate Sodium			S	Oral	17.5 Mg, Weekly (Qw)		Not Reported
	Methotrexate Sodium			S	Oral	15 Mg, Weekly (Qw)		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Ev 2 Weeks(Qow)		Not Reported
	Coversyl			C				Not Reported

	Ergocalciferol	C		2000 International Unit	Not Reported
	Leucovorin	C			Not Reported
	Folinic Acid	C			Not Reported
	Perindopril Erbumine	C	Oral	4 Milligram, Once Daily (Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	14909752	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018020609			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Actemra			S	Subcutaneous	Unknown		Not Reported
	Anakinra			S		Unknown		Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Codeine			S		Unknown		Not Reported
	Plaquenil			S	Oral	400 Mg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly (Qw) For 5 Years		Not Reported
	Humira			S	Subcutaneous	40 Mg, For 9 Years		Not Reported
	Methotrexate			S		25 Mg, Weekly (Qw) For 15 Years		Not Reported
	Orencia			S		Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Monthly (Qm) For 127 Days		Not Reported
	Sulfasalazine			S		Unknown Dose		Not Reported
	Hydroxychloroquine			S		400 Mg, Unk		Not Reported
	Xeljanz			C		Unknown		Not Reported

Prednisone	C	Unknown	Not Reported
Adalimumab	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	15285301	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2018CA021912			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Condition Aggravated; Contraindicated Product Administered; Drug Intolerance; Headache; Nausea; Off Label Use; Treatment Failure; Vomiting	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Morphine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	15922651	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2653466-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

Acetaminophen	C		Not Reported
Gabapentin	C		Not Reported
Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	15935383	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656801-00		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Therapy Duration-5 Month		Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Therapy Duration-6 Month		Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Adalimumab	S	Subcutaneous	Not Reported
	Rabeprazole Sodium	C	Oral	Not Reported
	Folic Acid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	15975815	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013003		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Joint Swelling; Off Label Use; Pneumonia; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Lidocaine Hydrochloride			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5.0 Milligram, Bid		Not Reported
	Cephalexin [Cefalexin]			C	Unknown	500 Milligram, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	16100906	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1025445		63 YR	Female	DEU

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

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Methotrexate	S	Subcutaneous	20 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram	Not Reported
	Methotrexate	S	Oral	20 Milligram	Mylan
	Methotrexate	S	Oral	20 Milligram	Mylan
	Apo-Hydroxyquine	S	Subcutaneous	Unk	Mylan
	Apo-Hydroxyquine	S	Subcutaneous	Unk	Mylan
	Apo-Hydroxyquine	S	Subcutaneous	Unk	Mylan
	Apo-Hydroxyquine	S	Subcutaneous	Unk	Mylan
	Apo-Hydroxyquine	S	Oral	Unk	Mylan
	Apo-Hydroxyquine	S	Unknown	Unk	Mylan
	Apo-Hydroxyquine	S	Unknown	Unk	Mylan
	Hydroxychloroquine	S	Oral	20 Milligram	Mylan
	Hydroxychloroquine	S	Oral	Unk	Mylan
	Hydroxychloroquine	S	Oral	Unk	Mylan
	Hydroxychloroquine	S	Subcutaneous	Unk	Mylan
	Hydroxychloroquine	S	Unknown	Unk	Mylan
	Methotrexate Sodium	S	Subcutaneous	20 Milligram	Mylan
	Methotrexate Sodium	S	Subcutaneous	20 Milligram	Mylan
	Methotrexate Sodium	S	Subcutaneous	20 Milligram	Mylan
	Methotrexate Sodium	S	Subcutaneous	Unk	Mylan
	Methotrexate Sodium	S	Oral	20 Milligram	Mylan
	Methotrexate Sodium	S	Oral	20 Milligram	Mylan
	Methotrexate Sodium	S	Oral	20 Milligram	Mylan
	Methotrexate Sodium	S	Oral	20 Milligram	Mylan
	Methotrexate Sodium	S	Oral	20 Milligram	Mylan
	Neoral	S	Subcutaneous	Unk	Mylan
	Neoral	S	Subcutaneous	Unk	Mylan
	Neoral	S	Subcutaneous	Unk	Mylan
	Neoral	S	Oral	Unk	Mylan

Neoral	S	Oral	Unk	Mylan
Humira	S	Intravenous (not otherwise specified)	Solution Subcutaneous	Mylan
Humira	S	Unknown	Solution Subcutaneous	Mylan
Humira	S	Subcutaneous	Unk	Mylan
Humira	S	Subcutaneous	Unk	Mylan
Humira	S	Subcutaneous	Solution Subcutaneous	Mylan
Ciclosporin	S	Unknown	Unk	Mylan
Ciclosporin	S	Subcutaneous	Unk	Mylan
Enbrel	S	Subcutaneous	50 Milligram, Qw	Mylan
Enbrel	S	Subcutaneous	50 Milligram, Qw	Mylan
Enbrel	S	Subcutaneous	50 Milligram, Qw	Mylan
Rituxan	S	Intravenous (not otherwise specified)	Unk	Mylan
Rituxan	S	Intravenous (not otherwise specified)	Unk	Mylan
Remicade	S	Intravenous (not otherwise specified)	3 Milligram	Mylan
Remicade	S	Intravenous (not otherwise specified)	3 Milligram	Mylan
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Mylan
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Mylan
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Mylan
Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram	Mylan
Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram	Mylan
Apo-Leflunomide	S	Oral	Unk	Mylan
Apo-Leflunomide	S	Unknown	Unk	Mylan

Orencia	S	Subcutaneous	125 Milligram		Mylan
Orencia	S	Subcutaneous	125 Milligram		Mylan
Orencia	S	Subcutaneous	125 Milligram		Mylan
Leflunomide	S	Unknown	Unk		Mylan
Leflunomide	S	Unknown	Unk		Mylan
Sulfasalazine	S	Oral	Unk		Mylan
Plaquenil /00072603/	S	Oral	Unk		Mylan
Plaquenil /00072603/	S	Unknown	Unk		Mylan
Rituximab	S	Intravenous (not otherwise specified)	Unk		Mylan
Rituximab	S	Oral	Unk		Mylan
Simponi	S	Subcutaneous	Unk		Mylan
Xeljanz	C	Unknown	2 Every 1 Day		Mylan
Xeljanz	C	Oral	10 Milligram, Qd (5 Mg, Bid)		Mylan
Xeljanz	C	Unknown	2 Ot, Qd		Mylan
Xeljanz	C	Oral	10 Milligram, Qd		Mylan
Xeljanz	C	Oral	10 Milligram, Qd (5 Mg, Bid)		Mylan
Xeljanz	C	Unknown	Unk		Mylan
Xeljanz	C	Oral	10 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	16252372	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-039070		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Neutropenia; Off Label Use; Red Blood Cell Sedimentation Rate Increased; Therapeutic Product Effect Incomplete;	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Unknown	776 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported

Therapeutic Response Decreased; Urinary Tract Infection	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qwk	Not Reported
	Methotrexate	C	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	C	Subcutaneous	25 Milligram	Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	C	Unknown	400 Milligram, Qwk	Not Reported
	Xeljanz	C	Unknown	5 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	400 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	16269769	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20190409745			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Otezla			S	Oral			Celgene
	Otezla			S				Celgene
	Cosentyx			S	Unknown			Not Reported
	Cosentyx			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S				Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Stelara			S				Not Reported

	Xeljanz	S	Unknown		Not Reported
	Xeljanz	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	16489780	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2059		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Blood Creatinine Decreased; Eye Pain; Fatigue; Glaucoma; Haematocrit Decreased; Haemoglobin Decreased; Headache; Inflammation; Lacrimation Increased; Lymphocyte Count Increased; Monocyte Count Increased; Nasopharyngitis; Nausea; Neutrophil Count Decreased; Ocular Procedural Complication; Optic Neuritis; Photophobia; Rheumatoid Arthritis; Synovitis; Tinnitus; Vision Blurred; White Blood Cell Count Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous	Cyclic: 4 Times/Week		Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydromorphone Hydrochloride			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown	Dose: 15.5 (Units Unknown)		Not Reported
	Plaquenil Sulfate			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported

	Apo-Acetaminophen	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Diphenhydramine Hydrochloride	C	Unknown	Not Reported
	Fosavance	C	Unknown	Not Reported
	Hydrocortisone	C	Unknown	Not Reported
	Hyzaar	C	Unknown	Not Reported
	Methylprednisolone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	16839343	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-088706		73 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cardiac Failure Congestive; Diverticulitis; Drug Ineffective; Dyspnoea; Eye Disorder; Lung Disorder; Product Dispensing Error; Pulmonary Toxicity; Sensitivity To Weather Change; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qcycle		Not Reported
	Arava			S	Unknown	10 Milligram, Qcycle		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, 1 Every 1 Week		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	1000 Milligram, 2 Every 1 Day	Not Reported
Prednisone	S	Unknown	1 Milligram, Every 1 Day	Not Reported
Prednisone	S	Unknown	5 Milligram	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	1 Gram, Q12h	Not Reported
Sulfasalazine	S	Unknown	500 Milligram, 2 Every 1 Day	Not Reported
Xeljanz	S	Oral	5 Milligram, 2 Every 1 Day	Not Reported
Acetaminophen;Oxycodone Hydrochloride	C	Unknown	2 Dosage Form, Qcycle	Not Reported
Asa	C	Unknown	325 Milligram	Not Reported
Bisoprolol	C	Unknown	5 Milligram, Every 1 Day	Not Reported
Endocet	C	Unknown	Unk	Not Reported
Endocet	C	Unknown	1 Dosage Form , 2 Every 1 Days	Not Reported
Folic Acid	C	Unknown	5 Milligram, Qcycle	Not Reported
Indomethacin [Indometacin]	C	Unknown	Unk	Not Reported
Macrogol	C	Unknown	Unk	Not Reported
Metoprolol	C	Unknown	75 Milligram, 2 Every 1 Day	Not Reported
Naproxen Sodium	C	Unknown	1000 Milligram, Qcycle	Not Reported
Pennsaid	C	Topical	Unk	Not Reported
Vitamin B 12	C	Unknown	Unk	Not Reported
D-Alpha Tocopherol	C	Unknown	12000 Milligram, Qd	Not Reported
Fish Oil	C	Unknown	12000 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	16933922	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2796105-00			Female	CAN

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

Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Lung Disorder; Platelet Count Decreased; Rheumatoid Arthritis; Septic Shock; Synovitis; Unevaluable Event; White Blood Cell Count Decreased	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Tofacitinib	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17225723	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2019M1131678		63 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Disease Progression; Dyspnoea; Fatigue; Gastrointestinal Disorder; Interstitial Lung Disease; Product Use In Unapproved Indication; Pulmonary Embolism	Methotrexate			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S		Unk		Mylan
	Rituximab			S	Unknown	1 G (Twice, 2 Week Apart), Cyclic(9 Cycles)		Mylan
	Rituximab			S	Unknown	Unk		Mylan
	Rituximab			S	Unknown	1 G, Bid		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17297595	EXPEDITED (15-DAY)		OT	CA-LUPIN HEALTHCARE (UK) LIMITED-2020-00254		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Dyspnoea; Gastric	Losartan Potassium			S	Unknown	Unk		Lupin
	Moxifloxacin Hydrochloride			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Cephalexin			S	Unknown	Unk (Tablet)		Lupin

Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Cephalexin	S	Unknown	Unk	Lupin
	Arava	S	Unknown	Unk	Not Reported
	Biaxin	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Biaxin	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Ciprofloxacin	S	Unknown	Unk	Not Reported
	Ciprofloxacin	S	Unknown	Unk	Not Reported
	Clindamycin Hydrochloride	S	Unknown	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enalapril Maleate	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Hydralazine Hydrochloride	S	Unknown	Unk	Not Reported
	Hydrochlorothiazide	S	Unknown	Unk	Not Reported
	Hydrochlorothiazide	S	Unknown	Unk	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram Every 1 Week	Not Reported
	Metoprolol Tartrate	S	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	S	Unknown	Unk	Not Reported
	Pariet	S	Unknown	Unk	Not Reported
	Penicillin G [Benzylpenicillin]	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Avelox	S	Unknown	Unk	Not Reported
	Penicillin Nos	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Cipro [Ciprofloxacin]	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	8.5 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Iron Sucrose	C	Unknown	Unk	Not Reported

	Esomeprazole		C	Unknown	Unk	Not Reported
	Gold		C	Unknown	Unk	Not Reported
	Saccharated Iron Oxide		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17356419	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1010578		57 YR	Female	FRA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17393907	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543740			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Acetaminophen;Codeine Phosphate	C		Not Reported
	Meloxicam	C		Not Reported
	Methotrexate	C	Unknown	Not Reported
	Synthroid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17393996	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2537096			Male	CAN

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394059	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3265441-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Rituximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394264	EXPEDITED (15-DAY)		OT	CA-ROCHE-2537887		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported

	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394399	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536713		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Spleen Disorder; Urticaria	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Cimzia			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394502	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-00		65 YR	Female	CAN

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

Obstructive Airways Disorder; Platelet Count Decreased; Pneumonitis; Pulmonary Mass; Restrictive Pulmonary Disease	Spiriva		S	Unknown		Boehringer Ingelheim
	Enbrel		S	Unknown		Not Reported
	Leflunomide		S	Oral		Not Reported
	Lipitor		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]		S	Oral		Not Reported
	Zenhale		S	Unknown		Not Reported
	Zenhale		S	Unknown	Aerosol, Metered Dose	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394504	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1181893		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Ciclosporin			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous	20 Mg		Barr
	Methotrexate			S				Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Endocervical		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394588	EXPEDITED (15-DAY)		OT	CA-ROCHE-2537191			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394661	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1179329			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urine Present; Drug Tolerance; Intentional Product Use Issue	Ciclosporin			S	Unknown			Ivax
	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394663	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2020-CA-1179313		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of	Alendronate Sodium			S	Unknown			Actavis
	Ciclosporin			S	Unknown			Ivax
	Codeine			S	Unknown			Not Reported
	Ibuprofen			S	Oral			Actavis
	Ibuprofen			S	Oral	600 Milligram Daily;		Actavis
	Leflunomide			S	Oral			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Methotrexate	S	Unknown		Barr
	Apo-Ibuprofen	S	Oral		Not Reported
	Apremilast	S	Unknown	120 Milligram Daily;	Not Reported
	Apremilast	S			Not Reported
	Apremilast	S			Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Infliximab	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Otezla	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	2000 Milligram Daily;	Not Reported
	Sulfasalazine	S	Endocervical		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Oxycodone	C	Unknown		Not Reported
	Benadryl	C	Unknown		Not Reported
	Colchicine	C	Unknown		Not Reported
	Dexilant	C	Oral		Not Reported
	Febuxostat	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported

	Gravol	C	Unknown	Not Reported
	Mogadon	C	Oral	Not Reported
	Nitrazepam	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Uloric	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394673	EXPEDITED (15-DAY)		OT	CA-ROCHE-2537374		71 YR	Female	CAN

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

	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394679	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540899			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Visual Impairment	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394727	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-007436		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394921	EXPEDITED (15-DAY)		OT	CA-ROCHE-2537338			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Cough; Drug Ineffective; Influenza; Nasopharyngitis; Nausea; Psoriasis; Rash	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394929	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0727			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Pain; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394930	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0712			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dactylitis; Dermatitis Psoriasiform; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Hypoacusis; Nausea; Psoriatic Arthropathy; Therapeutic Product Effect Incomplete; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Esomeprazole Magnesium-Naproxen Sodium			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394934	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3265597-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder; Gastric Disorder; Therapeutic Product Effect Decreased; Visual Field Defect	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17395045	EXPEDITED (15-DAY)		OT	CA-ROCHE-2538042			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17395100	EXPEDITED (15-DAY)		OT	CA-ROCHE-2537878			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Blood Cholesterol Increased; Bronchitis; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Dyspepsia; Fear; Hypertension; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Sleep Disorder; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Calcium Carbonate			C	Oral			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Hydromorphone			C	Oral			Not Reported
	Methotrexate			C	Oral			Not Reported
	Naproxen			C	Unknown			Not Reported
	Tylenol Arthritis Pain			C	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17395178	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540895			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17395295	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542486		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Intravenous (not otherwise specified)			Not Reported

	Ciclosporin	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Neoral	S	Oral	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17395317	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542479		63 YR	Female	CAN

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17395319	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542481		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine		S	Oral	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Neoral		S	Oral	Not Reported
	Neoral		S	Subcutaneous	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17395387	EXPEDITED (15-DAY)		OT	CA-ROCHE-2539792			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Asthenia; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17396501	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-007467			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic	Orencia			S	Unknown			Bristol Myers Squibb

Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17396506	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-007561			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17396588	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020052301			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Pancytopenia; Weight Decreased	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	1 G, 1 Every 12 Hours		Pfizer
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown	400 Mg, Unk		Not Reported
	Infliximab			C	Intravenous (not otherwise specified)	300 Mg, 1 Every 6 Weeks		Not Reported
	Infliximab			C	Intravenous (not otherwise specified)	200 Mg, Unk		Not Reported
	Infliximab			C	Intravenous (not otherwise specified)	300 Mg, 1 Every 8 Weeks		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk Unk, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17396931	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2020-001252		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Toxicity To Various Agents	Ibuprofen			S	Oral	Unk Unknown, Unknown		Par
	Hydroxychloroquine			S	Oral	6 G, Unknown		Not Reported
	Naproxen			S	Oral	Unk Unknown, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17398197	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2020054650			Female	CAN

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

Alopecia; Arthralgia; Asthma; Blister; Dyspepsia; Gastric Disorder; Oral Herpes; Oropharyngeal Pain; Pain In Extremity; Peripheral Swelling	Methotrexate Sodium	S		Unk		Pfizer
	Sulfasalazine	S		Unk		Pfizer
	Humira	S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Unk		Not Reported
	Prednisone	C		25 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17398288	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20200200441			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy	Otezla			S	Oral			Celgene
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	12811220	EXPEDITED (15-DAY)		OT	CA-UCBSA-2015025966		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered;	Cimzia			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported

Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Off Label Use; Viral Upper Respiratory Tract Infection	Plaquenil	S		Unk	Not Reported
	Enbrel	S	Subcutaneous	1 Df, Weekly (Qw)	Not Reported
	Tofacitinib	S	Oral	5 Mg, 2x/Day (Bid)	Not Reported
	Tofacitinib	S		Unk	Not Reported
	Tofacitinib	S	Oral	5 Mg, 2x/Day (Bid)	Not Reported
	Tofacitinib	S	Oral	5 Mg, 2x/Day (Bid)	Not Reported
	Tofacitinib	S	Oral	5 Mg, 2x/Day (Bid)	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk, Powder For Solution	Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Arava	C		Unk	Not Reported
	Prednisone	C	Oral		Not Reported
	Xeljanz	C	Oral	5 Milligram, 2x/Day (Bid)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	14299205	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050904		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Ear Infection; Fatigue; Fine Motor Skill Dysfunction; Malaise; Musculoskeletal Stiffness; Off Label Use; Pain; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	400 Mg, Weekly (Qw)		Not Reported
	Arava			S		20 Mg, Once Daily (Qd)		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly (Qw)		Not Reported
	Methotrexate			S		15 Mg, Weekly (Qw)		Not Reported
	Orencia			S		125 Mg, Unk		Not Reported
	Plaquenil			S		200 Mg, 2x/Day (Bid)		Not Reported
	Apo-Prednisone			S		5 Milligram		Not Reported

	Hydroxychloroquine Sulfate	S	200 Milligram, 2x/Day (Bid)	Not Reported
	Prednisone	S	Unk	Not Reported
	Prevacid	C	30 Mg, Once Daily (Qd)	Not Reported
	Folate	C	1 Milligram, Once Daily (Qd)	Not Reported
	Actonel	C	35 Mg, Weekly (Qw)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	14311631	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050957		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Anaemia; Arthralgia; Back Disorder; Blood Albumin Decreased; C-Reactive Protein Increased; Diverticular Perforation; Diverticulum; Drug Ineffective; Drug Intolerance; Hand Deformity; Headache; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphadenopathy; Musculoskeletal Stiffness; Neck Mass; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Spinal Operation; Surgery; Thrombocytosis	Cimzia			S	Subcutaneous	Unk		Not Reported
	Abatacept			S	Subcutaneous	125 Mg, Unk		Not Reported
	Apo-Methotrexate			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly (Qw)		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Weekly (Qw)		Not Reported
	Naprosyn			S		500 Mg, 2x/Day (Bid)		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Weekly (Qw)		Not Reported
	Plaquenil			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Ergocalciferol			C				Not Reported
	Folic Acid			C				Not Reported
	Gabapentin			C				Not Reported
	Lovastatin			C				Not Reported
	Metoprolol			C				Not Reported
	Pantoprazole			C				Not Reported
	Prednisone			S		20 Milligram		Not Reported
	Prednisone			S		2.5 Milligram, Weekly (Qw)		Not Reported
	Rosuvastatin Calcium			C				Not Reported
	Tramadol Hydrochloride			C				Not Reported
	Tofacitinib			C				Not Reported
	Naproxen			C				Not Reported

	Naproxen Sodium	C				Not Reported
	Vitamin D3	C		Unk		Not Reported
	Apo-Prednisone	S				Not Reported
	Orencia	S	Intravenous (not otherwise specified)	125 Milligram, Weekly (Qw)		Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	14496258	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007159		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Influenza; Injection Site Pain; Off Label Use; Pain; Pain In Extremity; Rheumatoid Arthritis; Skin Burning Sensation; Skin Exfoliation	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Allopurinol			C	Unknown			Not Reported
	Hydromorph Contin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	14921585	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044684			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Gait Inability; Joint Swelling; Mobility Decreased; Off Label Use; Rheumatoid Arthritis;	Orencia			S	Unknown			Bristol Myers Squibb
	Tramadol Hydrochloride			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Tramadol Hydrochloride			S	Unknown	Unk		Not Reported

Treatment Failure	Arava	C	Unknown		Not Reported
	Humira	C	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	C	Subcutaneous	25 Mg, Qwk	Not Reported
	Methotrexate	C	Oral	15 Unk, Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Simponi	C	Subcutaneous		Not Reported
	Xeljanz	C	Oral	5.0 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	15112426	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018028967			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Methotrexate			S		25 Mg, Weekly (Qw); Solution		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Tofacitinib Citrate			S		Unk		Not Reported
	Tofacitinib			S				Not Reported
	Leflunomide			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	15365414	NON-EXPEDITED			US-PFIZER INC-2018362153		76 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	15394855	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016039015		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1 Df, Weekly (Qw)		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Leflunomide			S				Not Reported
	Methotrexate Sodium			S				Not Reported
	Methotrexate Sodium			S	Oral	Solution		Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Sulfasalazine			S				Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	1 Dosgae Form, Ev 2		Not Reported

				Weeks(Qow)	
	Apo-Hydroxyquine	S		Unk	Not Reported
	Apo-Leflunomide	S		Unk	Not Reported
	Methotrexate	S		Unk	Not Reported
	Prednisone	C	Oral	6 Mg, Once Daily (Qd)	Not Reported
	Prednisone	C	Oral	10 Mg, Once Daily (Qd)	Not Reported
	Tylenol	C		Unk	Not Reported
	Advil	C		Unk	Not Reported
	Mefenamic Acid	C		Unk	Not Reported
	Dequalinium Chloride	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	15411214	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186666		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Feeding Disorder; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varenicline Tartrate			S	Oral	1.0 Dosage Forms		Not Reported
	Varenicline Tartrate			S	Oral	1 Doses Form		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Acetaminophen	C	Unknown	Not Reported
Oxycodone Hydrochloride	C	Unknown	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
Esomeprazole Magnesium Trihydrate	C	Oral	Not Reported
Esomeprazole Magnesium Trihydrate	C	Oral	Not Reported
Rosuvastatin Calcium	C	Oral	Not Reported
Valtrex	C	Oral	Not Reported
Valtrex	C	Unknown	Not Reported
Naproxen	C	Oral	Not Reported
Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	15608532	EXPEDITED (15-DAY)		HO, OT	CA-SHIRE-CA201843216			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	70 G, Unk		Shire
	Infliximab			S	Unknown	5 Mg, Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg/Kg, 1x/Week		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, 1x/Day:Qd		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, 4x A Week		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5 Mg/Kg, 1x/Day:Qd		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg/M2, 1x/Week		Not Reported
	Orencia			S	Intravenous (not	250 Mg, 1x A Month		Not Reported

In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting				otherwise specified)		
	Prednisone		S	Oral	5 Mg, 2x/Day:Bid	Not Reported
	Prednisone		S	Oral	3 Mg, Unk	Not Reported
	Tocilizumab		S	Intravenous (not otherwise specified)	280 Mg, Unk	Not Reported
	Sulfasalazine		S	Oral	250 Mg, 1x/Day:Qd	Not Reported
	Actemra		S	Intravenous (not otherwise specified)	280 Mg, 1x/Week	Not Reported
	Actemra		S	Intravenous (not otherwise specified)	280 Mg, 1x/2wks	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Kineret		S	Subcutaneous	50 Milligram, 1x/Day:Qd	Not Reported
	Apo-Naproxen		S	Unknown	Unk	Not Reported
	Apo-Naproxen		S	Unknown	Unk	Not Reported
	Apo-Prednisone		S	Oral	3.0 Milligram, 2x/Day:Bid	Not Reported
	Apo-Prednisone		S	Oral	5.0 Milligram	Not Reported
	Triamcinolone Acetonide		S	Intra-articular	Unk	Not Reported
	Triamcinolone		C	Other	Unk	Not Reported
	Triamcinolone Hexacetonide		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	15775641	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0586		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Abnormal; Carpal Tunnel Syndrome; Drug Ineffective; Fibromyalgia; General Physical Health Deterioration; Joint Swelling; Liver Function Test Increased;	Methotrexate (Trade Name Unknown)			S	Unknown	17.5 To 25 Mg		Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Plaquenil			S	Unknown			Not Reported

Neuropathy Peripheral; Osteoarthritis; Osteopenia; Radicular Pain; Rheumatoid Arthritis; Spinal Stenosis	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S			Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S			Not Reported
	Tramacet	S	Unknown		Not Reported
	Aclasta	S	Intravenous (not otherwise specified)	Single	Not Reported
	Tramadol/Acetaminophen	S	Oral		Not Reported
	Nortriptylin	C	Unknown	Once At Bedtime	Not Reported
	Nortriptylin	C	Unknown	Bedtime	Not Reported
	Metformin	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Lorazepam	C	Unknown	Once Nightly	Not Reported
	Vagifem	C	Unknown		Not Reported
	Lyrica	C	Oral		Not Reported
	Premarin	C	Unknown	Strength: 0.625mg	Not Reported
	Vitamin D	C	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Depomedrol	C	Intramuscular		Not Reported
	Depomedrol	C	Subcutaneous		Not Reported
	Depomedrol	C	Subcutaneous		Not Reported
	Tylenol Arthritis	C	Unknown		Not Reported
	Actonel Dr	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Methylprednisolone Acetate	C	Unknown		Not Reported

	Nortriptyline Hydrochloride	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Risedronate Sodium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	15975888	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-016370			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Blood Iron Abnormal; Condition Aggravated; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Pain; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	125 Milligram, Qd		Bristol Myers Squibb
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qwk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Gold			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	400 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	200 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Certolizumab			S	Unknown	200 Mg, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qwk		Not Reported
	Humira			S	Unknown	400 Mg, Qwk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	640 Mg, Q4wk		Not Reported
	Actemra			S	Unknown	640 Mg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	640 Milligram, Qmo		Not Reported

Actemra	S	Unknown	64 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	20 Milligram	Not Reported
Methotrexate	S	Oral	Unk, Qcycle	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	300 Unk	Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Cimzia	S	Subcutaneous	200 Milligram, Qwk	Not Reported
Apo-Azathioprine	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Qwk	Not Reported
Apo-Cyclosporine	S	Oral		Not Reported
Lyrica	S	Unknown		Not Reported
Rituxan	S	Unknown		Not Reported
Mycophenolate Mofetil	S	Unknown		Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Ciclosporin	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qwk	Not Reported
Hydroxychloroquine	S	Oral	200 Milligram, Bid	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Milligram, Qwk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulphate	S	Oral	400 Milligram, Qd	Not Reported
Certolizumab Pegol	S	Unknown	200 Milligram, Q2wk, Cyclical	Not Reported
Certolizumab Pegol	S	Subcutaneous	200 Milligram, Qwk, Cyclical	Not Reported
Pregabalin	S	Unknown	Unk	Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous		Not Reported
Tocilizumab	S	Unknown	640 Milligram, Qwk	Not Reported

Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram		Not Reported
Leflunomide	S	Unknown	Unk Unk, Qd		Not Reported
Xeljanz	S	Oral	5 Milligram, Bid		Not Reported
Methotrexate	S	Subcutaneous			Not Reported
Piroxicam	C	Unknown			Not Reported
Prednisone	C	Oral			Not Reported
Folic Acid	C	Unknown	5 Milligram		Not Reported
Methotrexate	C	Oral	25 Milligram, Qwk		Not Reported
Tofacitinib Citrate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	16447545	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-15412			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Fluid Retention; Joint Swelling; Memory Impairment; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Etanercept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Xeljanz			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	16631284	EXPEDITED (15-DAY)		HO, OT	CA-SHIRE-CA201923301			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive;	Human Normal Immunoglobulin			S	Intravenous (not	70 Gram		Shire

Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting			otherwise specified)		
	Human Normal Immunoglobulin	S	Unknown	Unk	Shire
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, 1x/2wks	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, 1x/Week	Not Reported
	Enbrel	S	Subcutaneous	12.5 Milligram, 4x A Week	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Milligram/Kilogram, 1x/Day:Qd	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, 1x/Week	Not Reported
	Infliximab	S	Unknown	5 Milligram	Not Reported
	Kineret	S	Subcutaneous	50 Milligram, 1x/Day:Qd	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, 1x/Week	Not Reported
	Naproxen	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Milligram, 1x A Month	Not Reported
	Prednisone	S	Oral	5 Milligram, 2x/Day:Bid	Not Reported
	Prednisone	S	Oral	3 Milligram	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, 1x/Day:Qd	Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Triamcinolone Hexacetonide	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous	150 Milligram, 1x/Day:Qd	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	16631288	EXPEDITED (15-DAY)		HO, OT	CA-SHIRE-CA201923310			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	70 Gram		Shire
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram		Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram, 4x A Week		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5 Milligram/Kilogram, 1x/Day:Qd		Not Reported
	Infliximab			S	Unknown	5 Milligram		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Milligram, 1x/Week		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram/Sq. Meter, 1x/Week		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, 1x A Month		Not Reported
	Prednisone			S	Oral	3 Milligram, 2x/Day:Bid		Not Reported
	Prednisone			S	Oral	5 Milligram, 2x/Day:Bid		Not Reported
	Sulfasalazine			S	Oral	250 Milligram, 1x/Day:Qd		Not Reported
	Triamcinolone Acetonide			S	Unknown	Unk		Not Reported
	Kineret			S	Subcutaneous	50 Milligram, 1x/Day:Qd		Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, 1x/Day:Qd		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	280 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	16689275	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-21899			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	16842040	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-27131		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anticipatory Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not	Unknown		Not Reported

			otherwise specified)		
Plaquenil	S	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Xeljanz	S	Oral			Not Reported
Xeljanz	S	Oral			Not Reported
Xeljanz	S	Oral			Not Reported
Acetaminophen	C	Unknown	Unknown		Not Reported
Cortisone Infiltration	C	Unknown	Unknown		Not Reported
Dexamethasone	C	Unknown	Unknown		Not Reported
Gabapentin	C	Unknown	Unknown		Not Reported
Reactine	C	Unknown	Unknown		Not Reported
Cetirizine Hydrochloride	C	Unknown	Unknown		Not Reported
Desoximetasone	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	16865618	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083770		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Off Label Use; Oral Discomfort; Product Use Issue; Treatment Failure; Uveitis	Orencia			S	Unknown			Bristol Myers Squibb
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Enbrel			S	Unknown			Not Reported

Rituxan	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Kevzara	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Xeljanz	S	Oral	5 Mg, Bid	Not Reported
Adalimumab	S	Subcutaneous	40 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	40 Milligram	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Unknown	20 Milligram	Not Reported
Methotrexate	S	Unknown	10 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
Sarilumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tofacitinib	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Rabeprazole Sodium	C	Oral	20 Mg, Unk	Not Reported
Methotrexate	C	Oral		Not Reported
Prednisone	C	Unknown	10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	16946347	EXPEDITED (15-DAY)		OT	NVSC2019FR010234		42 YR	Female	FRA

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

	Anakinra		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17146210	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2016038606		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Off Label Use; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Celebrex			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Dilaudid			S		Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Voltaren			S		Unk		Not Reported
	Diclofenac			S		Unk		Not Reported
	Diclofenac			S		Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Diclofenac Potassium			S		Unk		Not Reported
	Rituximab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17181501	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6011		61 YR	Female	CAN

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

Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Methotrexate (Trade Name Unknown)		S	Unknown	Not Reported
	Methotrexate (Trade Name Unknown)		S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)		S	Subcutaneous	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Orencia		S	Unknown	Not Reported
	Xeljanz		S	Unknown	Not Reported
	Xeljanz		S	Oral	Not Reported
	Actemra		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Arava		S	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17284429	EXPEDITED (15-DAY)		OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2020VAL000044			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Demerol			S	Unknown	Unk		Validus
	Plaquenil /00072603/			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Diphenhydramine Hydrochloride			S	Unknown	Unk		Not Reported
	Celecoxib			S	Oral	Unk		Not Reported

	Levofloxacin	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Azithromycin	S	Unknown	250 Mg, Qd	Not Reported
	Cyclophosphamide	S	Unknown	2000, Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Imuran /00001501/	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, 2 Every 1 Days	Not Reported
	Xeljanz	S	Oral	5 Mg, 2 Every 1 Days	Not Reported
	Xeljanz	S	Oral	5 Mg, 2 Every 1 Days	Not Reported
	Xeljanz	S	Oral	5 Mg, 2 Every 1 Days	Not Reported
	Ezetrol	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399264	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017051199		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Astigmatism; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective For Unapproved Indication; Dyspnoea; Hypersensitivity; Impaired Work Ability; Pain; Paraesthesia; Swelling; Therapeutic Product Effect Decreased; Vomiting	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Prednisone	C		10 Milligram, Once Daily (Qd)	Not Reported
Sulfadiazine	S		Unk	Not Reported
Baclofen	S		10 Milligram	Not Reported
Baclofen	S		Unk	Not Reported
Calcium Carbonate	C			Not Reported
Folic Acid	C			Not Reported
Hydromorphone	C			Not Reported
Methotrexate Sodium	S	Subcutaneous	Unk, Weekly (Qw)	Not Reported
Naproxen	S	Oral	500 Milligram, 2x/Day (Bid)	Not Reported
Tylenol [Paracetamol]	C			Not Reported
Vitamin D [Ergocalciferol]	C			Not Reported
Xeljanz	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399302	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202002000609			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Therapy Non-Responder	Hydroxychloroquine			S		Unk		Concordia
	Doxycycline			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399305	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202002000607			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Therapy Non-Responder	Hydroxychloroquine			S		Unk		Concordia
	Doxycycline			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399341	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202002000608			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Therapy Non-Responder	Hydroxychloroquine			S		Unk		Concordia
	Doxycycline			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399535	EXPEDITED (15-DAY)		OT	CA-ROCHE-2538479		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Tolerance Decreased; Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration;L- 6.0 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Therapy Duration;- 4.0 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Therapy Duration:- 730.0		Not Reported
	Cephalexin [Cefalexin]			C	Unknown			Not Reported
	Perindopril			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399635	EXPEDITED (15-DAY)		OT	CA-ROCHE-2538069			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Hepatic Cirrhosis; Synovitis; Treatment Failure; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399649	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543681			Female	CAN

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

	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399692	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-008175			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Orencia			S	Unknown	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram (One Every Two Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399767	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543683			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituxan	S	Intravenous drip	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Ciclosporin	S	Oral	Not Reported
	Ciclosporin	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Imuran [Azathioprine]	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Lyrica	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399847	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543705		67 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399861	EXPEDITED (15-DAY)		DE, OT	US-CIPLA LTD.-2020US00998			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suspected Suicide; Toxicity To Various Agents	Cyclobenzaprine			S	Oral	Unk		Invagen
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Amitriptyline			S	Oral	Unk		Not Reported
	Acetaminophen;Diphenhydramine Hydrochloride			S	Oral	Unk		Not Reported
	Tramadol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399923	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-006227		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Drug Interaction; Dyspnoea; Feeling Abnormal; Head Discomfort; Near Death Experience; Palpitations; Reading Disorder	Fluoxetine Dispersible Tablet			S	Unknown	1 Dosage Form, Once A Day		Aurobindo
	Plaquenil			S	Unknown	200 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400029	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0757			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400030	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0734			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Steatosis; Interstitial Lung Disease; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400078	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540883		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Actemra			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	730.0		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400088	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0744			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Nausea; Neuropathy Peripheral	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

	Arava	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400143	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540891			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400178	EXPEDITED (15-DAY)		OT	SE-ORION CORPORATION ORION PHARMA-20_00008421		59 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Neurosensory; Dizziness; Ear Discomfort; Nausea; Product Use In Unapproved Indication; Tinnitus	Methotrexate (Trade Name Unknown)			S	Unknown	"Nov 2016 Mtx Was Raised To 8 Tab / Week"		Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown	7 Tablet		Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown	6 Tablet		Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown	6 Tabs. Methotrexate / Week +5 Mg Prednisolone For Many Years		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400296	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542446		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Endocervical			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400415	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540935		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Simponi	S	Subcutaneous	Not Reported
	Desoximetasone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400475	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1182316			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400913	EXPEDITED (15-DAY)		OT	CA-ROCHE-2546059		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Intolerance; Drug Resistance; Hip Arthroplasty; Pulmonary Oedema; Therapeutic Product Effect Decreased;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Therapeutic Product Effect Incomplete	Etanercept	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	730.0 Days	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	C			Not Reported
	Actemra	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17401102	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543630		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Neck Pain	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17401148	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020004631		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Cimzia			S	Subcutaneous			Not Reported
	Arava			S		20 Milligram		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxyquinoline Sulfate			S				Not Reported
	Leflunomide			S		20 Milligram		Not Reported
	Methotrexate			S		25 Milligram		Not Reported
	Neoral			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Rapamune			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S		1 Gram		Not Reported
	Tacrolimus			S	Oral	2 Milligram, 2x/Day (Bid)		Not Reported
	Tacrolimus			S	Oral	3 Milligram, 2x/Day (Bid)		Not Reported
	Imuran [Azathioprine Sodium]			C		25 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17401431	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543719			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Extremity; Pain In Jaw; Rheumatoid Arthritis	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Gabapentin	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17401480	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543689			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17401574	EXPEDITED (15-DAY)		DE, OT	US-CIPLA LTD.-2020US00792			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suspected Suicide;	Meloxicam			S	Oral	Unk		Cipla

Toxicity To Various Agents	Cetirizine	S	Oral	Unk		Cipla
	Hydroxyzine	S	Oral	Unk		Invagen
	Hydroxychloroquine	S	Oral	Unk		Not Reported
	Butalbital, Acetaminophen & Caffeine	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17401828	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016038081		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Ear Infection; Fatigue; Fine Motor Skill Dysfunction; Malaise; Musculoskeletal Stiffness; Off Label Use; Pain; Rheumatoid Arthritis; Swelling	Cimzia			S	Subcutaneous	400 Mg, Weekly (Qw)		Not Reported
	Arava			S		20 Mg, Once Daily (Qd)		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly (Qw) 3.0 Month(S)		Not Reported
	Methotrexate Sodium			S		15 Mg, Weekly (Qw) 3.0 Month(S)		Not Reported
	Orencia			S		125 Mg, Unk		Not Reported
	Plaquenil			S		200 Mg, 2x/Day (Bid)		Not Reported
	Apo-Prednisone			S		5 Milligram		Not Reported
	Prednisone			S		Unk		Not Reported
	Prevacid			C		30 Mg, Once Daily (Qd)		Not Reported
	Actonel			C		35 Mg, Weekly (Qw)		Not Reported
	Folate			C		1 Mg, Once Daily (Qd)		Not Reported
	Folate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17401907	EXPEDITED (15-DAY)		OT	CA-ROCHE-2541324		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

Intolerance; Fatigue; Hand Deformity; Headache; Joint Swelling; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete				otherwise specified)	
	Arava		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17401991	EXPEDITED (15-DAY)		OT	CA-ROCHE-2541350		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Tolerance Decreased; Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown	Therapy Durationl- 6.0 Years		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Therapy Durationl- 4.0 Years		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Therapy Durationl-730.0		Not Reported
	Cephalexin [Cefalexin]			C	Unknown			Not Reported

	Perindopril	C	Unknown	Not Reported
	Hydroxychloroquine	C		Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17402084	EXPEDITED (15-DAY)		OT	NVSC2020CA033448		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Liver Function Test Increased; Palpitations; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure	Cosentyx			S	Subcutaneous	300 Mg, Qmo		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	1 Df (10 Mg), Qw		Not Reported
	Methotrexate			S	Oral	1 Df (15 Mg), Qw		Not Reported
	Methotrexate			S	Oral	1 Df (20 Mg), Qw		Not Reported
	Methotrexate			S	Oral	1 Df (25 Mg), Q3w		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	600 Mg, Unknown (1 Every Six Weeks)		Not Reported
	Sulfasalazine			S	Unknown	2 Df (1 G), Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qmo		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unknown		Not Reported
	Acetaminophen And Codeine			C	Unknown	325 Mg, Unknown		Not Reported
	Amitriptyline Hydrochloride			C	Unknown	Unk		Not Reported
	Baclofen			C	Unknown	Unk		Not Reported
	Betahistine Hydrochloride			C	Unknown	Unk		Not Reported
	Caffeine			C	Unknown	Unk		Not Reported
	Calcium			C	Unknown	Unk		Not Reported
	Clonidine Hydrochloride			C	Unknown	Unk		Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown	Unk		Not Reported
	Fluticasone Propionate			C	Unknown	Unk		Not Reported

	Folic Acid	C	Unknown	1 Df (5 Mg), Qd	Not Reported
	Folinic Acid	C	Unknown	Unk	Not Reported
	Gabapentin	C	Unknown	Unk	Not Reported
	Hydrochlorothiazide	C	Unknown	Unk	Not Reported
	Losartan	C	Unknown	Unk	Not Reported
	Metoprolol Tartrate	C	Unknown	Unk	Not Reported
	Mometasone Furoate	C	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	Unk	Not Reported
	Plaquenil	C	Unknown	1 Df (300 Mg), Qd	Not Reported
	Tylenol With Codeine	C	Unknown	Unk	Not Reported
	Aspirine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17402539	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20200200407		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Otezla			S	Oral			Celgene
	Actemra			S	Unknown			Celgene
	Apo-Leflunomide			S	Unknown			Celgene
	Arava			S	Unknown			Celgene
	Cimzia			S	Subcutaneous			Celgene
	Cosentyx			S	Unknown			Celgene
	Enbrel			S	Unknown	50 Milligram		Celgene
	Hydroxychloroquine			S	Unknown			Celgene
	Hydroxychloroquine Sulfate			S	Unknown			Celgene
	Infliximab			S	Unknown			Celgene
	Leflunomide			S	Unknown			Celgene
	Methotrexate			S	Unknown	25 Milligram		Celgene
	Orencia			S	Unknown			Celgene

Plaquenil	S	Unknown		Celgene
Simponi	S	Subcutaneous		Celgene
Sulfasalazine	S	Subcutaneous	50 Milligram	Celgene
Acetaminophen	C	Unknown		Celgene
Baclofen	C	Unknown	20 Milligram	Celgene
Calcium	C	Unknown	500 Milligram	Celgene
Dorzolamide Hydrochloride And Timolol Maleate	C	Ophthalmic		Celgene
Ergocalciferol	C	Unknown		Celgene
Ergocalciferol	C	Unknown		Celgene
Estradiol	C	Unknown	.6 Percent	Celgene
Estrogel	C	Unknown	.6 Percent	Celgene
Estrogel	C	Unknown		Celgene
Furosemide	C	Unknown	40 Milligram	Celgene
Gravol	C	Unknown		Celgene
Gravol Ginger	C	Unknown		Celgene
Levaquin	C	Unknown	50 Milligram	Celgene
Morphine	C	Unknown		Celgene
Potassium Chloride	C	Unknown	1500 Milligram	Celgene
Tofacitinib Citrate	C	Oral	10 Milligram	Celgene
Valsartan	C	Oral	320 Milligram	Celgene
Xalatan	C	Ophthalmic	50 Milligram	Celgene
Xeljanz	C	Oral	10 Milligram	Celgene
Zingiber Officinale	C	Oral	500 Milligram	Celgene

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17403018	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020059792		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cerebrovascular Accident; Diverticular	Calcium Carbonate			S				Pfizer

Perforation; Drug Hypersensitivity; Drug Intolerance; Insomnia; Joint Swelling; Knee Arthroplasty; Pain; Peripheral Swelling; Psoriasis; Psoriatic Arthropathy; Rash; Skin Reaction; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate Sodium		S		Unk	Pfizer
	Morphine Sulfate		S		Unk	Unknown
	Actemra		S	Unknown	Unk	Not Reported
	Alendronate Sodium		S		Unk	Not Reported
	Asa		S		Unk	Not Reported
	Fosinopril		S		Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S		Unk	Not Reported
	Simponi		S		Unk	Not Reported
	Synthroid		S		Unk	Not Reported
	Tylenol [Paracetamol]		S		Unk	Not Reported
	Tylenol [Paracetamol]		S	Unknown	Unk	Not Reported
	Vitamin D [Colecalciferol]		S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17403218	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020056477			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypertension; Nausea; Thrombocytopenia; Vomiting	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Orencia			S				Not Reported
	Arava			S				Not Reported
	Gold			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17403272	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020052595			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective;	Methotrexate Sodium			S	Unknown	25 G, Weekly		Pfizer

Overdose; Psoriatic Arthropathy	Sulfasalazine		S	Unknown	1 G, 2x/Day	Pfizer
	Cosentyx		S	Unknown	300 Mg, Unk	Not Reported
	Cosentyx		S	Unknown	450 Mg, Unk	Not Reported
	Hydroxychloroquine		S	Unknown	400 Mg, 1x/Day	Not Reported
	Leflunomide		C	Unknown	20 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17404196	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020054649			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Drug Hypersensitivity; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Pain; Nausea; Periarthritis; Pruritus; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Etanercept			C	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17407178	DIRECT	Y	HO, LT			28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia; Seizure	Hydroxychloroquine			S		Other Frequency:First Dose;		Not Reported
	Metoprolol			C				Not Reported
	Carvedilol			C				Not Reported
	Vitamin B12			C				Not Reported
	Vitamin D			C				Not Reported
	Lisinopril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	11231180	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2015214504		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Back Disorder; Blood Albumin Decreased; Bone Erosion; C-Reactive Protein Increased; Condition Aggravated; Condition Aggravated; Contraindicated Product Administered; Diverticular Perforation; Diverticulum; Drug Ineffective; Drug Intolerance; Hand Deformity; Headache; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphadenopathy; Musculoskeletal Stiffness; Neck Mass; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Thrombocytosis	Enbrel			S	Unknown	50 Milligram, Qwk		Unknown
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Apo-Methotrexate			S	Subcutaneous	Unk		Not Reported
	Abatacept			S	Subcutaneous	125 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Naprosyn			S	Unknown	500 Mg, 2x/Day		Not Reported
	Prednisone			S		Unk		Not Reported
	Prednisone			S		20 Mg, Daily		Not Reported
	Prednisone			S		2.5 Mg, Weekly		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Weekly		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	125 Mg, Weekly		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Unk		Not Reported
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Naprelan			C		1000 Mg, 1x/Day		Not Reported
	Folic Acid			C		5 Mg, 3 Times/Wk		Not Reported
	Folic Acid			C	Unknown	5 Mg, 4 Times/Wk		Not Reported
	Folic Acid			C		5 Mg, Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Crestor			C		Unk		Not Reported
	Metoprolol			C		50 Mg, Unk		Not Reported
	Metoprolol			C	Unknown	Unk		Not Reported

Gabapentin	C		Unk	Not Reported
Lovastatin	C		Unk	Not Reported
Vitamin D	C		Unk	Not Reported
Pantoprazole	C		Unk	Not Reported
Tramadol Hydrochloride	C		Unk	Not Reported
Naproxen	C	Unknown	500 Mg, 2x/Day	Not Reported
Naproxen Sodium	C	Unknown	1000 Mg, Qd	Not Reported
Rosuvastatin Calcium	C		Unk	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Rosuvastatin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	12913938	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091776			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Hip Arthroplasty; Intentional Product Use Issue; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Diclofenac Sodium	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	13571360	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017077269		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Methotrexate Sodium			S	Oral	25 Milligram, 1x/Day		Not Reported
	Methotrexate Sodium			S	Oral	25 Milligram, 1x/Day		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Myochrysine			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	14213267	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3758		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Iron Deficiency Anaemia; Joint Effusion;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Tuberculin Test Positive	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral		Not Reported
	Remicade	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Cimzia	S	Subcutaneous	Cyclic	Not Reported
	Cimzia	S	Subcutaneous	Cyclical	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Cyclic (Once Every 2 Weeks)	Not Reported
	Humira	S	Subcutaneous	Cyclical	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	14446503	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0985		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Abnormal; Drug	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Ineffective; Impaired Work Ability; Nasopharyngitis; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	2times/Wk	Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Celebrex	S	Oral		Not Reported
	Celebrex	S	Unknown		Not Reported
	Vioxx	S	Oral		Not Reported
	Vioxx	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported

	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	14632688	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-020006		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Off Label Use; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Qd		Not Reported
	Arava			S	Unknown	10 Mg, Qd		Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1500 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Anakinra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	15259069	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0134		76 YR	Female	CAN

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

Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Inappropriate Schedule Of Product Administration; Incorrect Route Of Product Administration; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Vaginal	4 Times/Week	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	4 Times/Week	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	2 Times/Week	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Cyclic	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	Cyclic	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Cyclic	Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported

Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Xeljanz	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Intramuscular		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Arava	S			Not Reported
Rituximab	S	Unknown		Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Day 1 &15	Not Reported
Ativan	C	Unknown		Not Reported
Cortisone	C	Intramuscular		Not Reported
Cortisone	C	Intra-articular		Not Reported
Darifenacin Hydrobromide	C	Unknown		Not Reported
Darifenacin Hydrobromide	C	Unknown		Not Reported
Dilaudid	C	Unknown		Not Reported
Benadryl	C	Unknown	As Necessary	Not Reported
Furosemide	C	Unknown		Not Reported
Loperamide	C	Unknown		Not Reported
Norflex	C	Unknown		Not Reported
Omnaris	C	Unknown		Not Reported
Pantoloc	C	Unknown		Not Reported
Synthroid	C	Unknown		Not Reported

Vagifem	C	Vaginal	Not Reported
Leflunomide	C	Unknown	Not Reported
Abatacept	C	Unknown	Not Reported
Kineret	C	Unknown	Not Reported
Lasix	C	Unknown	Not Reported
Enablex	C	Unknown	Not Reported
Enablex	C	Unknown	Not Reported
Desoximetasone	C	Unknown	Not Reported
Acetaminophen	C	Unknown	Not Reported
Codeine	C	Unknown	Not Reported
Hydromorphone	C	Unknown	Not Reported
Kadian	C	Unknown	Not Reported
Oxyneo	C	Unknown	Not Reported
Restasis	C	Unknown	Not Reported
Trimethoprim	C	Unknown	Not Reported
Urispas	C	Unknown	Not Reported
Morphine Sulfate	C	Unknown	Not Reported
Diphenhydramine	C	Unknown	Not Reported
Dexamethasone	C	Unknown	Not Reported
Darifenacin	C	Unknown	Not Reported
Dyclone	C	Unknown	Not Reported
Kenalog	C	Unknown	Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown	Not Reported
Plantago Ovata	C	Unknown	Not Reported
Dyclonine Hydrochloride	C	Unknown	Not Reported
Anakinra	C	Unknown	Not Reported
Laxisoft	C	Unknown	Not Reported
Pantoprazole Sodium	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported

	Triamcinolone Acetonide		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	15328824	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175343			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	15711487	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587408-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Sounds Abnormal; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)	
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Abatacept	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Actonel	C		Not Reported
	Alprazolam	C		Not Reported
	Amlodipine	C	Oral	Not Reported
	Acetylsalicylic Acid	C		Not Reported
	Bisoprolol Fumarate	C		Not Reported
	Celebrex	C		Not Reported
	Ergocalciferol	C		Not Reported
	Folic Acid	C		Not Reported
	Metformin	C		Not Reported
	Pantoprazole	C		Not Reported
	Paroxetine	C		Not Reported
	Prednisone	C		Not Reported
	Risedronate	C		Not Reported
	Simvastatin	C		Not Reported
	Telmisartan	C		Not Reported
	Xeljanz	C		Not Reported
	Statex	C		Not Reported
	Mtx	C		Not Reported
	Morphine Sulphate	C		Not Reported
	Asa	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	15838856	NON-EXPEDITED			US-PFIZER INC-2019013915		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	16073865	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2703788-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Pain; Nausea; Neck Pain; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rash; Therapeutic Product Effect Decreased; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	Solution		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Rituximab			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	16080945	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013872		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug	Rosuvastatin			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Azathioprine		S	Unknown	Unk	Not Reported
	Cimzia		S	Subcutaneous	Unk	Not Reported
	Enbrel		S	Subcutaneous	Unk	Not Reported
	Gold		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sodium Aurothiomalate		S	Intramuscular	Unk	Not Reported
	Xeljanz		C	Oral	5 Milligram, Two Times A Day	Not Reported
	Cephalexin		C	Unknown	500 Milligram, Four Times/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	16689873	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-21418		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Pain;	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Plaquenil	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Cetirizine Hydrochloride	C	Unknown		Not Reported
	Desoximetasone	C	Unknown	Unknown	Not Reported
	Dexamethasone	C	Unknown	Unknown	Not Reported
	Gabapentin	C	Unknown		Not Reported
	Reactine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	16726516	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20181202738		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Psoriatic	Otezla			S	Oral			Celgene
	Cimzia			S	Subcutaneous			Not Reported

Arthropathy; Synovitis	Cosentyx	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Plaquenil	S	Oral	Not Reported
	Remicade	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	16949982	EXPEDITED (15-DAY)		HO	NVSC2019DE011861			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Pulmonary Sepsis; Respiratory Failure; Septic Encephalopathy	Erelzi			S	Unknown	50 Mg, Qw		Novartis
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported

Sulfasalazine	S	Unknown	3000 Mg, Qd	Not Reported
Sulfasalazine	S	Unknown	3000 Mg, Qd	Not Reported
Sulfasalazine	S	Unknown	3000 Mg, Qd	Not Reported
Sulfasalazine	S	Unknown	3000 Mg, Qd	Not Reported
Sulfasalazine	S	Unknown	3000 Mg, Qd	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	1000 Mg, Qd	Not Reported
Sulfasalazine	S	Unknown	3000 Mg, Qd	Not Reported
Leflunomide	S	Unknown	20 Mg	Not Reported
Leflunomide	S	Unknown	20 Mg	Not Reported
Leflunomide	S	Unknown	20 Mg	Not Reported
Leflunomide	S	Unknown	20 Mg	Not Reported
Leflunomide	S	Unknown	20 Mg	Not Reported
Leflunomide	S	Unknown	20 Mg	Not Reported
Leflunomide	S	Unknown	20 Mg	Not Reported
Leflunomide	S	Unknown	20 Mg	Not Reported
Leflunomide	S	Unknown	20 Mg	Not Reported
Leflunomide	S	Unknown	20 Mg	Not Reported
Leflunomide	S	Unknown	20 Mg	Not Reported
Leflunomide	S	Unknown	20 Mg	Not Reported
Leflunomide	S	Unknown	20 Mg	Not Reported
Leflunomide	S	Unknown	20 Mg	Not Reported
Leflunomide	S	Unknown	20 Mg	Not Reported
Leflunomide	S	Unknown	20 Mg	Not Reported
Leflunomide	S	Unknown	20 Mg	Not Reported
Leflunomide	S	Unknown	20 Mg	Not Reported
Leflunomide	S	Unknown	20 Mg	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	250 Mg	Not Reported
Hydroxychloroquine	S	Unknown	250 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17360452	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202001000506			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Decreased; Rheumatoid Arthritis; Vitamin D Decreased	Hydroxychloroquine			S	Unknown	Unk; Tablet		Concordia
	Aubagio			S	Oral	14 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17405028	EXPEDITED (15-DAY)		OT	CA-ROCHE-1749484		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Peripheral Swelling; Rash; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17405412	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-008648			Female	CAN

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

Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia		S	Intravenous (not otherwise specified)		Bristol Myers Squibb
	Actemra		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Cetirizine Hydrochloride		S	Unknown	10 Milligram	Not Reported
	Cimzia		S	Unknown	Unk	Not Reported
	Cortisone Acetate		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Folic Acid		S	Unknown		Not Reported
	Fosamax		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Phthalylsulfathiazole		S	Unknown	Unk	Not Reported
	Prednisone		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17405500	EXPEDITED (15-DAY)		OT	CA-ROCHE-2545008			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal	Rivotril			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Cefixime			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Nifedipine	S	Unknown	Not Reported
	Pantoprazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Zantac	S	Unknown	Not Reported
	Zopiclone	S	Unknown	Not Reported
	Morphine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17406023	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0777			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Asthma; Blister; Dyspepsia; Gastric Disorder; Oral Herpes; Oropharyngeal Pain; Pain In Extremity; Peripheral Swelling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17406024	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0776			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Pancytopenia; Weight Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Hydroxychloroquine	C	Unknown	Not Reported
	Infliximab	C	Unknown	Not Reported
	Infliximab	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17406028	EXPEDITED (15-DAY)		HO	CA-ROCHE-2542434			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Naproxen Sodium			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17406750	EXPEDITED (15-DAY)		DS	CA-ROCHE-2542981		8 YR	Female	CAN

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17407002	EXPEDITED (15-DAY)		OT	SE-ACCORD-172239		59 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Neurosensory; Dizziness; Ear Discomfort; Nausea; Tinnitus	Methotrexate			S		7 Tablets		Accord
	Plaquenil			S				Not Reported
	Prednisolone			C				Not Reported
	Methotrexate			S		6 Tablets		Accord
	Methotrexate			S		6 Tab. Methotrexate / V +5 Mg Prednisolone For Many Years		Accord
	Methotrexate			S		In November 2016 Mtx Was Increased To 8 Tab / V		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17407019	EXPEDITED (15-DAY)		OT	CA-ROCHE-2546720		60 YR	Female	CAN

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

Drug Ineffective; Rheumatoid Arthritis	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Imuran [Azathioprine]	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17407735	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543731			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Rabeprazole Sodium			C	Unknown			Not Reported

	Methotrexate			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17407796	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020056860		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Drug Ineffective; Off Label Use; Product Use In Unapproved Indication; Product Use Issue	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Unknown			Pfizer
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 1x/Day		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 1 Every 12 Hours		Not Reported
	Prednisone			S	Oral	50 Mg, 1x/Day		Not Reported
	Prednisone			S	Oral	20 Mg, 1x/Day		Not Reported
	Immunoglobulin G Human			C	Intravenous (not otherwise specified)	Unk Unk, Monthly		Not Reported
	Immunoglobulin G Human			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17407906	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20200201452			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Otezla			S	Oral			Celgene
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Stelara	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17408807	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023723			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S				Not Reported
	Prednisone			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17409234	EXPEDITED (15-DAY)		OT	NVSC2020CA037016			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction; Premature Baby	Calcium			S	Transplacental	Unk		Novartis
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Aspirin			S	Transplacental	162 Mg, Qd		Not Reported
	Enoxaparin			S	Transplacental	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17409348	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020060642			Female	CAN

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

Alopecia; Back Injury; Confusional State; Drug Ineffective; Fall; Headache; Injury; Muscular Weakness; Nausea; Off Label Use; Treatment Failure; Vomiting	Methotrexate Sodium	S		25 Mg, Weekly	Pfizer
	Sulfasalazine	S		Unk	Pfizer
	Arava	S		20 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk (1 Every 2 Weeks)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Mg, 1x/Day	Not Reported
	Orencia	S		Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Unk, 1x/Day	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17410838	EXPEDITED (15-DAY)		OT	SE-PFIZER INC-2020062383		59 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Neurosensory; Dizziness; Ear Discomfort; Nausea; Off Label Use; Product Use In Unapproved Indication; Tinnitus	Methotrexate Sodium			S		8 Df, Weekly (Mtx Was Raised To 8 Tab / Week)		Pfizer
	Methotrexate Sodium			S		6 Df, Unk		Pfizer
	Methotrexate Sodium			S		7 Df, Unk		Pfizer
	Methotrexate Sodium			S		6 Df, Weekly (Methotrexate / Week)		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Prednisolone			C		5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17411055	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-03977			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug	Infliximab			S	Unknown	Unknown		Not Reported

Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Certolizumab Pegol	S	Unknown	Unknown	Not Reported
	Golimumab	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	Unknown Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Otezla	S	Unknown	Unknown	Not Reported
	Plaquenil	C	Unknown	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Unknown	Not Reported
	Ventolin Hfa	C	Unknown	Unknown Metered-Dose (Aerosol))	Not Reported
	Xeljanz	C	Unknown	Unknown	Not Reported
	Acetaminophen	C	Unknown	Unknown	Not Reported
	Advair	C	Unknown	Unknown	Not Reported
	Allopurinol	C	Unknown	Unknown	Not Reported
	Atrovent Hfa	C	Unknown	Unknown Metered-Dose (Aerosol)	Not Reported
	Codeine	C	Unknown	Unknown	Not Reported
	Cyclobenzaprine Hydrochloride	C	Unknown	Unknown	Not Reported
	Hydromorphone Hydrochloride	C	Unknown	Unknown	Not Reported
	Ibuprofen	C	Unknown	Unknown	Not Reported
	Leucovorin Calcium	C	Unknown	Unknown	Not Reported
	Nexium Dr	C	Unknown	Unknown	Not Reported
	Dilaudid	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17411060	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-03965			Female	CAN

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

Drug Ineffective; Drug Intolerance; Erythema; Gastric Ulcer; Hepatic Function Abnormal; Liver Function Test Increased; Skin Exfoliation	Etanercept		S	Unknown	Unknown	Not Reported
	Amlodipine Besilate		S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Oral		Not Reported
	Leflunomide		S	Unknown	Unknown	Not Reported
	Methotrexate		S	Unknown	Unknown	Not Reported
	Naproxen		S	Unknown	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17411068	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-03811			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Large Intestine Infection	Etanercept			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17411069	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-03822			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive;	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported

Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Synovitis	Etanercept	S	Unknown	Unknown	Not Reported
	Actemra	S	Unknown	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Unknown	Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Certolizumab Pegol	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Leflunomide	S	Endocervical	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methylprednisolone	S	Unknown	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Xeljanz	S	Unknown	Unknown	Not Reported
	Naproxen	C	Unknown	Unknown	Not Reported
	Prednisone	C	Unknown	Unknown	Not Reported
	Rituxan	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17411076	EXPEDITED (15-DAY)		HO	DE-SAMSUNG BIOEPIS-SB-2019-36506		83 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticular Perforation; Diverticulitis	Benepali			S	Subcutaneous			Not Reported
	Hcq			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17411086	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-03839			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Inflammation; Rheumatoid Arthritis	Etanercept			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Methotrexate			C	Unknown	Unknown		Not Reported
	Prednisone			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17411089	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-03835		35 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type	Etanercept			S	Unknown			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	Unknown		Not Reported
	Methotrexate			S	Oral	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unknown	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17411442	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-006473			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Density Abnormal; Depression; Neuropathy Peripheral	Ramipril			S	Unknown	12.5 Milligram, Once A Day		Aurobindo
	Arava			S	Unknown	Unk		Not Reported
	Bisoprolol			S	Unknown	12.5 Milligram, Once A Day		Not Reported
	Buprenorphine			S	Unknown	10 Microgram, Once A Day		Not Reported
	Calcium			S	Unknown	Unk		Not Reported
	Cyanocobalamin			S	Unknown	Unk		Not Reported
	Fish Oil			S	Unknown	Unk		Not Reported
	Lasix			S	Unknown	20 Milligram		Not Reported
	Magnesium Gluconate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rivaroxaban			S	Unknown	15 Milligram, Once A Day		Not Reported
	Pyridoxine Hydrochloride			S	Unknown	Unk		Not Reported
	Pyridoxine Hydrochloride			S	Unknown	Unk		Not Reported

	Vitamin D	S	Unknown	Unk		Not Reported
	Furosemide;Potassium Chloride	S	Unknown	20 Milligram		Not Reported
	Magnesium	S	Unknown	Unk		Not Reported
	Vitamin B6	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	11214316	EXPEDITED (15-DAY)		OT	AU-ROCHE-1596702		52 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Skin Lesion; Treatment Failure	Mycophenolate Mofetil			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown	For One Month		Not Reported
	Prednisone			S	Unknown	For More Than 3 Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	11688844	EXPEDITED (15-DAY)		OT	GB-ACCORD-034909		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Lethargy; Myelodysplastic Syndrome	Methotrexate			S	Unknown			Accord
	Metformin			S	Unknown			Accord
	Humira			S	Unknown	40 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	12919683	EXPEDITED (15-DAY)		OT	CA-ROCHE-1850264		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported

Intolerance; Intentional Product Use Issue; Nausea; Off Label Use; Prescribed Overdose	Celebrex		S	Unknown	Not Reported
	Celebrex		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Subcutaneous	Not Reported
	Simponi		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	13190997	EXPEDITED (15-DAY)		HO	CA-ROCHE-1888707		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Neoplasm; Immune System Disorder; Lyme Disease	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	15298019	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20180803448		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia;	Otezla			S	Oral			Celgene
	Actemra			S	Unknown			Not Reported

Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Sleep Disorder; Sleep Disorder	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Minocycline Hydrochloride	S	Unknown		Not Reported
	Myochrysine	S	Parenteral		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sirukumab	S	Unknown		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral	10 Milligram	Not Reported
	Plaquenil	S	Unknown		Not Reported
	Salazopyrin	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Minocycline	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Certolizumab Pegol	S	Subcutaneous		Not Reported
	Etanercept	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Minocin	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tofacitinib Citrate	S	Oral	10 Milligram	Not Reported
	Ustekinumab	S	Unknown		Not Reported
	Methotrexate	C	Unknown	15 Milligram	Not Reported

	Abatacept	C	Unknown		Not Reported
	Orencia	C	Unknown	250 Milligrams	Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	15730589	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20181202419			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Otezla			S	Oral			Celgene
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	15930195	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2654210-00		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Oral			Not Reported
	Arava			S	Oral			Not Reported

Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Cimzia		S	Subcutaneous	Single-Use Pre-Filled Syringe	Not Reported
	Codeine		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Plaquenil		S	Oral		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Unknown		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Prednisone		C			Not Reported
	Xeljanz		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	16093680	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2709127-00			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	16388002	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-029948			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Incomplete; Treatment Noncompliance	Celecoxib Capsules			S	Unknown	200 Milligram, Once A Day		Aurobindo
	Citalopram			S	Unknown	20 Milligram, Once A Day		Aurobindo
	Sertraline			S	Unknown	25 Milligram		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Indomethacin			S	Unknown	50 Milligram, 3 Times A Day		Not Reported
	Indomethacin			S				Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Oral	10 Milligram		Not Reported
	Temazepam			S	Unknown	Unk		Not Reported
	Toradol			S	Intramuscular	10 Milligram		Not Reported
	Toradol			S				Not Reported
	Zopiclone			S	Unknown	7.5 Milligram		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Lidocaine			C	Unknown	Unk		Not Reported
	Methylprednisolone Acetate			C	Unknown	80 Milligram		Not Reported
	Naproxen			C	Unknown	500 Milligram, Two Times A Day		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Vitamin D			C	Unknown	50000 International Unit, Every Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	16413232	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044080		47 YR	Female	CAN

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

Arthralgia; Arthritis; Burning Sensation; Drug Ineffective; Incorrect Route Of Product Administration; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Orencia	S	Unknown	750 Milligram	Bristol Myers Squibb
	Cimzia	S	Subcutaneous	Unknown	Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Tofacitinib	S	Unknown		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Rabeprazole Sodium	C	Oral	20 Milligram, Qd	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Tofacitinib Citrate	S	Unknown		Not Reported
	Kevzara	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	16586116	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557146-00		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Incorrect Route Of Product Administration; Infection; Infection; Pneumonia; Pneumonia; Synovitis	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	16716446	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20190803878		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Liver Function Test Increased;	Otezla			S	Oral			Celgene
	Cosentyx			S	Subcutaneous	300 Milligram		Not Reported

Palpitations; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Infliximab	S	Intravenous drip	600 Milligram	Not Reported
	Infliximab	S	Unknown	400 Milligram	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Oral	20 Milligram	Not Reported
	Methotrexate	S	Oral	10 Milligram	Not Reported
	Methotrexate	S	Oral	15 Milligram	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Unknown	25 Milligram	Not Reported
	Sulfasalazine	S	Unknown	2 Gram	Not Reported
	Sulfasalazine	S			Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram	Not Reported
	Hydrochlorothiazide	S	Oral	25 Milligram	Not Reported
	Clonidine Hydrochloride	C	Oral		Not Reported
	Esomeprazole Magnesium Trihydrate	C	Oral	40 Milligram	Not Reported
	Fluticasone Propionate	C	Unknown		Not Reported
	Gabapentin	C	Oral	2000 Milligram	Not Reported
	Folinic Acid	C	Unknown		Not Reported
	Folic Acid	C	Unknown	5 Milligram	Not Reported
	Losartan	C	Unknown		Not Reported
	Metoprolol Tartrate	C	Oral	100 Milligram	Not Reported
	Mometasone Furoate	C	Nasal	50 Microgram	Not Reported
	Naproxen	C	Unknown		Not Reported
	Plaquenil	C	Unknown	300 Milligram	Not Reported

Acetaminophen And Codeine	C	Oral	325 Milligram		Not Reported
Amitriptyline Hydrochloride	C	Oral	50 Milligram		Not Reported
Aspirin	C	Unknown	81 Milligram		Not Reported
Baclofen	C	Unknown	20 Milligram		Not Reported
Betahistine Hydrochloride	C	Oral	16 Milligram		Not Reported
Caffeine	C	Oral			Not Reported
Calcium	C	Unknown	1000 Milligram		Not Reported
Clonidine	C	Unknown			Not Reported
Amoxicillin Trihydrate/Clarithromycin/Esomeprazole Magnesium Trihydrat	C	Unknown			Not Reported
Acetaminophen	C	Oral			Not Reported
Acetaminophen	C	Unknown	325 Milligram		Not Reported
Codeine	C	Oral			Not Reported
Codeine	C	Unknown	325 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17218862	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019548324		76 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Application Site Erythema; Drug Ineffective; Hypoacusis; Off Label Use; Product Use Issue; Psoriatic Arthropathy	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, Daily (Qd)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Oral	400 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17395434	EXPEDITED (15-DAY)		HO	BR-STRIDES ARCOLAB LIMITED-2020SP001169		32 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dental Caries; Dental	Tacrolimus			S	Unknown	2 Milligram Per Day		Strides

Necrosis; Off Label Use; Tooth Abscess; Tooth Fracture; Toothache	Prednisolone		S	Unknown	5 Milligram Per Day	Not Reported
	Alendronate		S	Oral	70 Milligram, Once A Week	Not Reported
	Hydroxychloroquine		S	Unknown	400 Milligram Per Day	Not Reported
	Tamoxifen		C	Unknown	10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17411606	EXPEDITED (15-DAY)		DS	CA-ROCHE-2540641		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use Issue; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	4.0 Years		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	404.0 Days		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	5.0 Years		Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported

Cell Count Increased	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17411609	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-235348		11 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Gastroenteritis Cryptosporidial; Hypogammaglobulinaemia ; Tachycardia	Methotrexate			S	Unknown			Sun
	Hydroxychloroquine			S	Unknown			Sun
	Mycophenolate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17411672	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542957		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Urticaria	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Lyrica			C				Not Reported
	Marijuana			C	Unknown			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Oxycodone			C				Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17411767	EXPEDITED (15-DAY)		HO	CA-ROCHE-2539868			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17411790	EXPEDITED (15-DAY)		DS	CA-ABBVIE-20K-028-3270161-00		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Influenza; Injection Site Pain; Pain; Rheumatoid Arthritis; Skin Burning Sensation; Skin Exfoliation	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Simponi		S	Subcutaneous	Not Reported
	Allopurinol		C		Not Reported
	Hydromorph Contin		C		Not Reported
	Prednisone		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17411845	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543626			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17411893	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0796			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Overdose; Psoriatic Arthropathy	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412024	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0799			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypertension; Nausea; Thrombocytopenia; Vomiting	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412049	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0803			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Drug Hypersensitivity; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Pain; Nausea; Periarthritis; Pruritus; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Etanercept			C	Unknown			Not Reported
	Humira			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412097	EXPEDITED (15-DAY)		HO	US-ZYDUS-047509		94 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Cardiac Event; Dizziness	Hydroxychloroquine			S	Oral			Zydus Pharm
	Albuterol			C	Unknown			Not Reported
	Apixaban			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Vitamin D			C	Unknown			Not Reported
	Carvedilol			C	Unknown			Not Reported
	Loratadine			C	Unknown			Not Reported
	Erythromycin			C	Unknown			Not Reported
	Fluticasone			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Isosorbide			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Warfarin			C	Unknown			Not Reported
	Clopidogrel			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412105	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540711			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412152	EXPEDITED (15-DAY)		OT	CA-ROCHE-2546734		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412232	EXPEDITED (15-DAY)		OT	SE-TEVA-2020-SE-1184606		59 YR	Female	SWE

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

Deafness Neurosensory; Dizziness; Ear Discomfort; Nausea; Tinnitus	Methotrexate	S	Unknown	"Nov 2016, Mtx Was Raised To 8 Tab/V".	Barr
	Methotrexate	S	Unknown	7 Tablets	Barr
	Methotrexate	S	Unknown	6 Tablets	Barr
	Methotrexate	S	Unknown	"6 Tab. Methotrexat/V +5 Mg Prednisolon For Many Years".	Barr
	Plaquenil	S	Unknown		Not Reported
	Prednisolone	C		5mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412298	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3270872-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Impaired Work Ability; Joint Stiffness; Mobility Decreased; Muscular Weakness; Musculoskeletal Stiffness; Nausea; Ototoxicity; Pain In Extremity; Spinal Pain; Vomiting	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412387	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540889			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported

Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412439	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540929			Female	CAN

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

Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Acetaminophen	S	Endocervical		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Synthroid	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Meloxicam	C			Not Reported
	Acetaminophen;Codeine Phosphate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412841	EXPEDITED (15-DAY)		CA, HO, OT	GR-LUPIN PHARMACEUTICALS INC.-2020-00745			Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aorta Hypoplasia; Bradycardia Foetal; Congenital Aortic Stenosis; Echocardiogram Abnormal; Foetal Exposure During Pregnancy; Heart Block Congenital; Neonatal Respiratory Distress; Ventricular Septal Defect	Hydroxychloroquine			S	Transplacental	Unk		Lupin
	Acetylsalicylic Acid			S	Transplacental			Not Reported
	Prednisolone			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413195	EXPEDITED (15-DAY)		OT	CA-ROCHE-2546739			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413199	EXPEDITED (15-DAY)		OT	CA-ROCHE-2546743		57 YR	Female	CAN

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

Animal Bite; Drug Ineffective; Emotional Disorder; Herpes Zoster; Inappropriate Schedule Of Product Administration; Malignant Melanoma; Mobility Decreased; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Restasis	C	Oral	Not Reported
	Sulfasalazine	C	Oral	Not Reported
	Synthroid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413260	EXPEDITED (15-DAY)		OT	CA-SA-2020SA036521			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Topicort			S				Sanofi
	Alendronate Sodium			S				Not Reported
	Arava			S				Sanofi
	Cetirizine Hydrochloride			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Sanofi
	Methotrexate			S				Not Reported
	Folic Acid			S	Subcutaneous	1 Mg		Not Reported
	Prednisone			S				Not Reported
	Sulfasalazine			S				Not Reported
	Actemra			S	Topical			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413280	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543697		38 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413281	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543642			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Head Injury; Road Traffic Accident	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413326	EXPEDITED (15-DAY)		HO	CA-ROCHE-2546133			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Viread			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413355	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543703			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Therapeutic Response Decreased; Therapy Non-Responder	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413693	EXPEDITED (15-DAY)		OT	CA-ROCHE-2546111			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413707	EXPEDITED (15-DAY)		HO, OT	IN-MYLANLABS-2020M1016074		41 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acinetobacter Infection; Brain Abscess; Drug Ineffective; Hydrocephalus; Nocardiosis; Septic Shock; Shunt Infection	Methotrexate			S	Unknown	10 Milligram, Qw		Not Reported
	Meropenem			S	Intravenous (not otherwise specified)			Not Reported
	Meropenem			S				Not Reported
	Prednisolone			S	Unknown	30 Milligram, Qd		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Mylan
	Trimethoprim Sulfamethoxazole			S	Intravenous (not otherwise specified)	15 Mg/Kg Of Trimethoprim Divided In Three Doses		Mylan
	Trimethoprim Sulfamethoxazole			S				Mylan
	Amikacin			S	Intravenous (not	7.5 Milligram/Kilogram		Mylan

					otherwise specified)					
	Amikacin			S						Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413936	EXPEDITED (15-DAY)		OT	CA-BAXTER-2020BAX002879			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Procytox (Cyclophosphamide) 2000mg/Vial			S	Intravenous (not otherwise specified)	Dosage Form- Not Specified		Baxter
	Arava			S	Unknown	Dosage Form- Tablets		Not Reported
	Azithromycin			S	Unknown	Dosage Form- Not Specified		Not Reported
	Azithromycin			S	Unknown	Dosage Form- Not Specified		Not Reported
	Benadryl			S	Unknown	Dosage Form- Not Specified		Not Reported
	Celebrex			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Dosage Form- Solution Subcutaneous Single-Use Prefilled Syringe		Not Reported
	Demerol			S	Unknown	Dosage Form- Not Specified		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form- Solution Subcutaneous		Not Reported
	Imuran			S	Unknown	Dosage Form- Not Specified		Not Reported
	Levofloxacin			S	Unknown	Dosage Form- Not Specified		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Dosage Form Not Specified		Not Reported
	Plaquenil			S	Unknown	Dosage Form- Tablets		Not Reported

	Simponi		S	Subcutaneous	Dosage Form- Solution Subcutaneous	Not Reported
	Xeljanz		S	Oral		Not Reported
	Xeljanz		S	Oral		Not Reported
	Xeljanz		S	Oral		Not Reported
	Xeljanz		S	Oral		Not Reported
	Ezetrol		C	Unknown	Dosage Form- Tablets	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413946	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2020M1017169		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Retinal Toxicity	Hydroxychloroquine			S	Unknown	Later, Restarted At The Time Of Pregnancy Until 26weeks Of Gestational		Not Reported
	Azathioprine			S	Unknown	Initial Dosage Not Stated. Later, At The Time Of Pregnancy She Was Maintained On150 Mg Daily.		Not Reported
	Azathioprine			S	Unknown	150 Milligram, Qd		Not Reported
	Azathioprine			S	Unknown	175 Milligram, Qd		Not Reported
	Nifedipine			S	Unknown	30 Milligram, Bid		Not Reported
	Prednisone			S	Unknown	5 Milligram, Qd		Mylan
	Prednisone			S	Unknown	40 Milligram, Qd		Mylan
	Acetylsalicylic Acid			S	Unknown	162 Milligram, Qd		Mylan
	Methylprednisolone			C	Intravenous (not otherwise specified)	1 Gram		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413953	EXPEDITED (15-DAY)		OT	CA-ROCHE-2546719			Female	CAN

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

Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Desoximetasone	C		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17414259	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020058166		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Balance Disorder; Cardiac Disorder; Dermatitis Allergic; Drug Hypersensitivity; Foot Deformity; Hand Deformity; Infection; Irritable Bowel Syndrome; Lung Neoplasm Malignant; Pain In Extremity; Therapeutic Product Effect Decreased; Toe Amputation	Methotrexate Sodium			S	Oral	10 Mg, Unk		Pfizer
	Arava			S		Unk		Not Reported
	Gold			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil S			S		Unk		Not Reported
	Arnica Montana			C		Unk		Not Reported
	Asa			C		Unk		Not Reported
	Calcium			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17415069	EXPEDITED (15-DAY)		OT	CA-ROCHE-2546744		36 YR	Male	CAN

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

Arthralgia; Condition Aggravated; Drug Ineffective; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities	Rituxan	S	Intravenous (not otherwise specified)	Therapy Duration 184.0	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Therapy Duration 0.0	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Therapy Duration 3.0 Years	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Therapy Duration 7.0 Months	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Etanercept	S	Unknown	Therapy Duration 31.0	Not Reported
	Arava	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17415209	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020058429		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Adrenal Disorder; Amnesia; Arthralgia; Asthma; Blood Pressure Increased; Bronchitis; Burning Sensation; Cough; Diarrhoea; Dysgeusia; Dyspnoea; Emotional Distress; Emphysema; Fatigue; Furuncle; Genital Herpes Simplex; Head Injury; Headache; Herpes Virus Infection; Hypertension; Inflammation; Injection Site Erythema; Injection Site Induration; Injection Site Inflammation; Injection Site Pruritus;	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Quetiapine Fumarate			S	Unknown			Not Reported
	Arava			S	Oral	20 Mg, 1x/Day		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 1x/Day		Not Reported
	Alendronate Sodium			C				Not Reported
	Amlodipine			C				Not Reported
	Ativan			C	Unknown	Unk Unk, As Needed		Not Reported
	Lipitor			C				Not Reported
	Methadone			C	Oral	10 Mg, 1x/Day		Not Reported

Insomnia; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Rash; Respiratory Failure; Rhinorrhoea; Secretion Discharge; Sleep Disorder; Urine Odour Abnormal; Weight Increased	Pantoloc [Pantoprazole]	C			Not Reported
	Prednisone	C	Unknown		Not Reported
	Valtrex	C			Not Reported
	Zopiclone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17415269	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183886			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17415270	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184218		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Swelling;	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported

Toxicity To Various Agents; Visual Impairment	Orencia		S	Unknown		Not Reported
	Methotrexate		C	Subcutaneous		Not Reported
	Methotrexate		C	Subcutaneous		Not Reported
	Sulfasalazine		C	Oral	1 Gram Daily;	Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17415271	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183917			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17415275	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1184182			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Fall; Gait Disturbance; Mobility Decreased; Peripheral Swelling; Therapeutic Response Decreased	Leflunomide			S	Unknown			Barr
	Arava			S	Oral	200 Milligram Daily;		Not Reported
	Lovenox			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17415297	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA032797		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Neuropathy Peripheral; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Sleep Disorder; Spinal Stenosis	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Novartis
	Aclasta			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Acetaminofen Tramadol			S	Oral	Unk		Not Reported
	Arava			S	Unknown	20 Mg		Not Reported
	Actonel			C	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	2 G, Qd		Not Reported
	Calcium			C	Unknown	Unk		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Lyrica			C	Unknown	Unk		Not Reported
	Metformin			C	Unknown	Unk		Not Reported
	Methylprednisolone Acetate			C	Unknown	Unk		Not Reported
	Nortriptyline			C	Unknown	Unk		Not Reported
	Nortriptyline Hydrochloride			C	Unknown	Unk		Not Reported
	Premarin			C	Unknown	Unk		Not Reported
	Tylenol 8 Hr Arthritis Pain			C	Unknown	Unk		Not Reported
	Vagifem			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17415389	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183894			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Malaise; Nausea; Retinal Toxicity; Vomiting	Leflunomide			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Azathioprine			C	Oral	100 Milligram Daily;		Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17415556	EXPEDITED (15-DAY)		CA, OT	NVSC2020GR035293			Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia Foetal; Foetal Exposure During Pregnancy; Heart Disease Congenital; Respiratory Distress	Acetylsalicylic Acid			S	Unknown	Unk, (Maternal Dose: Unk)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk, (Maternal Dose: Unk)		Novartis
	Prednisolone			S	Unknown	Unk, (Maternal Dose: Unk)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	11752885	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2015121181		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Blood Pressure Fluctuation; Body Temperature	Enbrel			S	Subcutaneous	Unk		Amgen
	Prednisone			S	Oral	25 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	50 Milligram		Not Reported
	Prednisone			S	Oral	3 Milligram, Qd		Not Reported
	Prednisone			S	Oral	50 Milligram, Qwk		Not Reported

Decreased; Bone Density Abnormal; Chills; Cough; Deafness; Decreased Appetite; Disability; Drug Ineffective; Drug Intolerance; Fatigue; Headache; Hypercholesterolaemia; Infection; Insomnia; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Oropharyngeal Pain; Pain; Pain In Extremity; Peripheral Swelling; Pyrexia; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Rosacea; Somnolence; Stress; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event; Vomiting; Weight Increased	Humira	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
	Indocid	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg, Qd	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Indomethacin	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	480 Milligram, Cyclical	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Gold (198 Au)	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	50 Milligram	Not Reported
	Apo-Prednisone	S	Oral	3 Milligram, Qd	Not Reported
	Apo-Prednisone	S	Oral	25 Milligram, Qd	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25,Unk, Qd	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, Qd	Not Reported

Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Cimzia	S	Subcutaneous	Unk (Single Use Prefilled Syringe)	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
Indometacin	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Acetaminophen	S	Oral	650 Milligram	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	S	Oral	50 Milligram	Not Reported
Methylprednisolone Sodium Succinate	S	Intravenous (not otherwise specified)	100 Milligram	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported
Xeljanz	C	Oral	Unk Unk, Bid	Not Reported
Folic Acid	C	Oral	Unk, Qwk	Not Reported
Folic Acid	C	Oral	5 Milligram, Unk	Not Reported
Cymbalta	C	Oral	30 Milligram, 30 Mg, Qd At Nights	Not Reported
B Complex [Vitamin B Complex]	C		Unk	Not Reported
Ciprodex [Ciprofloxacin Lactate]	C		Unk	Not Reported
Fish Oil	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	12212678	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016036511		76 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthritis; Cardiac Failure Congestive; Diverticulitis;	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	20 Milligram, Cyclical		Not Reported
	Arava			S	Unknown	10 Milligram, Cyclical		Not Reported

Drug Ineffective; Dyspnoea; Eye Disorder; Joint Swelling; Lung Disorder; Musculoskeletal Pain; Peripheral Swelling; Pulmonary Toxicity; Sensitivity To Weather Change; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Vascular Graft	Arava	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram, Bid	Not Reported
	Sulfasalazine	S	Unknown	1 Gram, Bid	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Plaquenil	S	Unknown	1000 Milligram, Bid	Not Reported
	Plaquenil	S	Unknown	200 Milligram, 2 Every 1 Day	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Prednisone	S	Unknown	1 Milligram, Qd	Not Reported
	Prednisone	S	Unknown	5 Milligram	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Celecoxib	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Lax-A-Day	C		Unk, Occ	Not Reported
	Vitamin B12	C	Sublingual	1200 Microgram, Qd	Not Reported
	Endocet	C		5+325 Mg, 1 Tablet 2 Times Per Day Prn	Not Reported
	Endocet	C		1 Dose 2 Every 1 Day	Not Reported
	Indomethacin	C		Unk	Not Reported
	Pennsaid	C		Unk	Not Reported
	Oxycocet	C		2 Tabs, 4-5x/Week	Not Reported
	Asa	C		325 Milligram, Occ	Not Reported
	Naprelan	C		1000 Milligram, Cyclical	Not Reported
	Metoprolol	C		75 Milligram, Bid	Not Reported
	Folic Acid	C		5 Milligram, Cyclical	Not Reported
	Bisoprolol	C		5 Milligram, Qd	Not Reported

Omega 3	C	12000 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	12337536	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016055447		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Leucovorin			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Apo-Hydroxyquine			C		Unk		Not Reported
	Calcium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	13348182	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017039391		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment	Enbrel			S	Unknown	Unk		Amgen
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported

Failure	Plaquenil	S	Unknown	200 Mg, Bid	Not Reported
	Kevzara	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Triatec [Ramipril]	C		Unk	Not Reported
	Atasol	C		Unk	Not Reported
	Tylenol	C	Unknown	650 Mg, Bid	Not Reported
	Atacand	C	Unknown	Unk	Not Reported
	Hydrodiuril	C		Unk	Not Reported
	Vitamin D	C		Unk	Not Reported
	Folic Acid	C		Unk	Not Reported
	Premarin	C		Unk	Not Reported
	Neurontin	C		600 Mg, Tid	Not Reported
	Acetaminophen	C		650 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	13782530	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017103905		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Sulfasalazine	S	Unknown	Unk		Not Reported
Methotrexate	C	Oral	Unk Unk, Qwk		Not Reported
Morphine	C	Topical	Unk, Every Two Days		Not Reported
Erythromycin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	14187184	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017170219			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Ineffective; Drug Intolerance; Feeding Disorder; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Enbrel			S	Unknown	50 Milligram, Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Varenicline Tartrate			S	Oral	Unk Unk, Qd		Not Reported
	Varenicline Tartrate			S	Oral	1 Dosage Form, Qd		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Rituximab			S	Intravenous (not			Not Reported

			otherwise specified)		
	Tofacitinib Citrate	C	Unknown	Unk	Not Reported
	Valtrex	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Rosuvastatin Calcium	C	Unknown	Unk	Not Reported
	Esomeprazole Magnesium W/Naproxen	C	Unknown	Unk	Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	Unk	Not Reported
	Acetaminophen	C		Unk	Not Reported
	Naproxen	C		Unk	Not Reported
	Oxycodone Hydrochloride	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	14246850	EXPEDITED (15-DAY)		HO	CA-ROCHE-2028708		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities;	Rituximab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported

Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Humira	S	Subcutaneous	Not Reported
	Codeine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Myochrysine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Oral	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Prednisolone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	15291603	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20180803571		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Psoriatic Arthropathy; Synovitis	Otezla			S	Oral	60 Milligram		Celgene
	Otezla			S	Oral			Celgene
	Otezla			S	Oral			Celgene
	Otezla			S	Oral			Celgene
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cosentyx			S	Unknown	300 Milligram		Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Infliximab			S	Intravenous drip	500 Milligram		Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	.6 Milliliter		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Pencillin (Benzyl Penicillin)			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	15399793	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083448			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	15635328	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105928			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Bone Erosion; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Exostosis; Foot Deformity;	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Headache; Hepatic Cirrhosis; Infection; Joint Dislocation; Joint Stiffness; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Pneumonia; Synovitis	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Minocycline Hydrochloride	S	Unknown		Not Reported
	Otezla	S	Oral	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous drip	Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sirukumab	S	Unknown		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Minocycline	S	Unknown		Not Reported
	Cosentyx	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Morphine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Dilaudid	C	Unknown		Not Reported
	Wellbutrin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	15842727	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016021061		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Methotrexate			S	Oral	20 Milligram, Unk		Not Reported

Intolerance; Fatigue; Hepatic Enzyme Increased; Nausea; No Adverse Event; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Factor Positive; Synovitis; Treatment Failure; Vomiting	Methotrexate	S	Subcutaneous	20 Milligram, Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Unk	Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram, Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Unk	Not Reported
	Methotrexate	S	Unknown	Unk Unk, Qd	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Milligram, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Ciclosporin	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	200 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Neoral	S	Subcutaneous	Unk	Not Reported
	Neoral	S	Oral	Unk	Not Reported
	Neoral	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Milligram	Not Reported
	Orencia	S	Subcutaneous	125 Milligram, Unk	Not Reported

Orencia	S	Subcutaneous	12.5 Milligram, Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
Apo-Hydroxyquine	S	Oral	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Oral	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Xeljanz Xr	C		Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Xeljanz	S	Unknown	Unk, Qd	Not Reported
Xeljanz	S	Oral	10 Milligram, Qd	Not Reported
Xeljanz	S	Unknown	Unk Unk, Qd	Not Reported
Methotrexate Sodium	S	Subcutaneous	20 Milligram	Not Reported
Simponi	C	Subcutaneous	Unk	Not Reported
Actemra	C	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Unk	Not Reported
Actemra	C	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Unk	Not Reported
Actemra	C	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Unk	Not Reported
Actemra	C	Intravenous (not otherwise specified)	8 Milligram, Unk	Not Reported
Actemra	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	15866486	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1094		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fall; Fatigue; Femur Fracture; Hepatic Enzyme Increased; Infection; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Off Label Use; Osteoporosis; Pain; Rash; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Naproxen			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Naroxin			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Risedronate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

	Methotrexate Sodium		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	16636557	EXPEDITED (15-DAY)		OT	CA-009507513-1907CAN014720		31 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Desloratadine			S	Unknown	5 Mg		Merck
	Singulair			S	Unknown	10 Mg. Dosage Form: Not Specified		Merck
	Apo Prednisone			S	Unknown	Unk		Not Reported
	Apo Ranitidine			S	Unknown	150.0 Mg, 2 Every 1 Day		Not Reported
	Cetirizine Hydrochloride			S	Unknown	20.0 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Not Reported
	Ketotifen Fumarate			S	Unknown	4.0 Mg, 2 Every 1 Days		Not Reported
	Cromolyn Sodium			S	Unknown	200 Mg, 3 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17352131	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1175498		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antisynthetase Syndrome; Rebound Effect	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17417570	EXPEDITED (15-DAY)		OT	BR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-236079		32 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis; Dental Necrosis; Tooth Abscess	Alendronic Acid			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Sun
	Prednisone			S	Unknown	Unk		Mutual

	Tacrolimus	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17417966	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184031		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Mobicox			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Depo-Medrol			C	Intra-articular	80 Milligram Daily;		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418219	EXPEDITED (15-DAY)		HO	US-ZYDUS-047474		11 YR	Female	USA

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

Cryptosporidial; Hypogammaglobulinaemia ; Leukopenia; Neutropenia	Hydroxychloroquine		S	Unknown	Zydus Pharm
	Mycophenolic Acid		S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418399	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543618		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty	Actemra			S	Unknown			Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Desoximetasone			C				Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418405	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543745		43 YR	Male	CAN

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

Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Actonel	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418434	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543742			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418479	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543690		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown	4.0 Months		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418537	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543627		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Product Use Issue; Red Blood Cell Sedimentation Rate	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous	Therapy Duration:- 5.0 Years		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration:- 11.0 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Abnormal	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Esomeprazole Magnesium Trihydrate		C		Not Reported
	Folic Acid		C	Unknown	Not Reported
	Naproxen		C	Unknown	Not Reported
	Xeljanz		C	Oral	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418616	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0811		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cerebrovascular Accident; Diverticular Perforation; Drug Hypersensitivity; Drug Intolerance; Insomnia; Joint Swelling; Knee Arthroplasty; Pain; Peripheral Swelling; Psoriasis; Psoriatic Arthropathy; Rash; Skin Reaction; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Calcium Carbonate			S	Unknown			Not Reported
	Morphine Sulfate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Asa			S	Unknown			Not Reported
	Fosinopril			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Synthroid			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported
	Vitamin D			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418650	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184235		70 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418682	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1184190		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous	1.4286 Milligram Daily;		Barr
	Methotrexate			S	Unknown	1.7857 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous	2.1429 Milligram Daily;		Barr
	Methotrexate			S	Unknown	1.4286 Milligram Daily;		Barr
	Methotrexate			S	Unknown	1.7143 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous	2.5 Milligram Daily;		Barr
	Methotrexate			S	Unknown	1.7143 Milligram Daily;		Barr
	Methotrexate			S	Unknown	1.4286 Milligram Daily;		Barr
	Alendronate Sodium			S	Unknown	10 Milligram Daily;		Actavis
	Codeine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown	12 Milligram Daily;		Not Reported

Daily Activities; Panniculitis; Peripheral Swelling; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Enbrel	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine/00072603/	S	Unknown		Not Reported
	Methotrexate	S	Oral	1.4286 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown	2000 Milligram Daily;	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418684	EXPEDITED (15-DAY)		LT	CA-TEVA-2020-CA-1184211			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418688	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183936		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Leflunomide			S	Unknown	20 Milligram Daily;		Barr

Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Methotrexate	S	Subcutaneous	2.1429 Milligram Daily;		Barr
	Actemra	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
	Orencia	S	Unknown			Not Reported
	Sulfasalazine	S	Oral	1 Gram Daily;		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418705	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183932		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Leflunomide			S	Unknown	1 Dosage Forms Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Risedronate Sodium			S	Unknown	5 Milligram Daily;		Teva
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	1 Dosage Forms Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418744	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0844		66 YR	Female	CAN

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

Atrial Fibrillation; Drug Ineffective; Off Label Use; Product Use In Unapproved Indication	Methotrexate (Trade Name Unknown)		S	Unknown	Not Reported
	Methotrexate (Trade Name Unknown)		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Prednisone		S	Oral	Not Reported
	Prednisone		S	Oral	Not Reported
	Immunoglobulin G Human		C	Unknown	Not Reported
	Immunoglobulin G Human		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418787	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0827			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Confusional State; Drug Ineffective; Fall; Headache; Injury; Muscular Weakness; Nausea; Off Label Use; Treatment Failure; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418909	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3275098-00		59 YR	Male	CAN

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

Cerebral Disorder; Drug Ineffective; Head Injury; Rheumatoid Arthritis; Synovitis	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Hydroxychloroquine		S	Oral	Not Reported
	Cimzia		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418955	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543692		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Restasis			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419040	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1183361		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal	Leucovorin			S	Unknown			Barr

Independence In Daily Activities; Pollakiuria; Product Dose Omission	Methotrexate		S	Unknown		Barr
	Leflunomide		S	Oral	20 Milligram Daily;	Barr
	Prednisone		S	Unknown		Actavis
	Actemra		S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe		S	Unknown		Not Reported
	Humira		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown	200 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419072	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007699		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Retinal Toxicity	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Mycophenolate			S	Unknown	1 G, Bid		Novartis
	Methylprednisolone			C	Intravenous (not otherwise specified)	1 G, (For 2 Days)		Not Reported
	Prednisone			C	Unknown			Not Reported
	Azathioprine			C	Unknown	100 Mg, Qd		Not Reported
	Cyclophosphamide			C	Intravenous (not otherwise specified)	500 Mg, Every Two Weeks For Six Doses		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419141	EXPEDITED (15-DAY)		DS	CA-ROCHE-2543637		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported

Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Skin Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Cimzia		S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Oral		Not Reported
	Hydroxychloroquine		S	Oral		Not Reported
	Hydroxychloroquine		S	Oral		Not Reported
	Methotrexate		S	Oral		Not Reported
	Methotrexate		S	Oral		Not Reported
	Orencia		S	Subcutaneous		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral		Not Reported
	Prednisone		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz		S	Oral		Not Reported
	Xeljanz		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419152	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183879		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Orencia	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Acetaminophen	C	Unknown			Not Reported
Mefenamic Acid	C	Unknown			Not Reported
Prednisone	C	Oral	10 Milligram Daily;		Not Reported
Prednisone	C	Oral	6 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419155	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1183858		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Cefazolin			S	Unknown			Not Reported
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous	3.5714 Milligram Daily;		Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Naproxen			C	Unknown	1000 Milligram Daily;		Not Reported
	Viread			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419158	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543730		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder; Therapy Partial Responder	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419171	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2020-CA-1184234		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug	Leflunomide			S				Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Intra-arterial			Barr
	Methotrexate			S				Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Oxycodone			S	Unknown			Actavis

Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Actemra	S	Unknown	Not Reported
	Actemra	S		Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Arava	S		Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Gold	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S		Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
	Cannabis Sativa	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Rituximab	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419181	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543711			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Caffeine			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Dorzolamide Hydrochloride			C	Ophthalmic			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Meprobamate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Timolol Maleate			C	Ophthalmic			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419243	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183915		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Enzyme Increased; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Arava	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxyquinoline Sulfate	S	Unknown	Not Reported
	Neoral	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rapamune	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tacrolimus	S	Oral	Not Reported
	Tacrolimus	S	Oral	Not Reported
	Imuran	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419259	EXPEDITED (15-DAY)		DS	CA-ROCHE-2543752			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

	Prednisone		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419385	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184192		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder; Liver Injury	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419404	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184227			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Perforation; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419406	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1184201		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr

Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure	Indometacin	S	Unknown		Actavis
	Prednisone	S	Oral	25 Milligram Daily;	Actavis
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Methotrexate	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Cymbalta	C	Oral	30 Milligram Daily;	Not Reported
	Folic Acid	C	Oral		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419417	EXPEDITED (15-DAY)		OT	IN-JNJFOC-20200210530			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Meconium Aspiration Syndrome; Pneumonia Aspiration; Pulmonary Arterial Hypertension; Respiratory Distress	Cetirizine Hydrochloride			S	Transplacental	10 Milligram, 2x/Day (Bid)		Not Reported
	Prednisolone			S	Transplacental	5 Milligram, Once Daily (Qd)		Not Reported
	Hydroxychloroquine			S	Transplacental	200 Milligram, Once Daily (Qd)		Not Reported
	Sulphasalazine			S	Transplacental	1 Gram, Once Daily (Qd)		Not Reported
	Naproxen			S	Transplacental	500 Mg Sos		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419447	EXPEDITED (15-DAY)		HO	CA-ROCHE-2543639			Female	CAN

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

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Hypercalcaemia; Infusion Related Reaction; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Skin Ulcer	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419459	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543751			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Piroxicam	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419536	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543693		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Investigation Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419543	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543636			Female	CAN

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

Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Gabapentin	C	Unknown	Not Reported
	Tylenol 8 Hr Arthritis Pain	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419562	EXPEDITED (15-DAY)		OT	CA-ROCHE-2547861			Female	CAN

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

Sulfate]

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419637	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0861		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Adrenal Disorder; Amnesia; Arthralgia; Asthma; Blood Pressure Increased; Bronchitis; Burning Sensation; Cough; Diarrhoea; Dysgeusia; Dyspnoea; Emotional Distress; Emphysema; Fatigue; Furuncle; Genital Herpes Simplex; Head Injury; Headache; Herpes Virus Infection; Hypertension; Inflammation; Insomnia; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Rash; Respiratory Failure; Rhinorrhoea; Secretion Discharge; Sleep Disorder; Urine Odour Abnormal; Weight Increased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Quetiapine Fumarate			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Alendronate Sodium			C	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Lipitor			C	Unknown			Not Reported
	Methadone			C	Unknown			Not Reported
	Pantoloc			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Valtrex			C	Unknown			Not Reported
	Zopiclone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419638	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-844506		56 YR	Female	CAN

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

Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Actonel	S	Unknown		Teva
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Leflunomide	S	Unknown	20 Milligram Daily;	Barr
	Methotrexate	S	Subcutaneous		Barr
	Plaquenil	S	Unknown	300 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419785	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543704			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Neck Pain; Off Label Use; Rheumatoid Factor Positive; Spinal Column Injury; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419860	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1183922		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Off Label Use; Osteoporosis; Pain; Rash; Synovitis	Leflunomide			S	Oral			Barr
	Naproxen			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419889	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183510		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cerebrovascular Accident; Diverticular Perforation; Drug Hypersensitivity; Drug Intolerance; Insomnia; Joint Swelling; Knee Arthroplasty; Pain; Peripheral Swelling; Psoriasis; Psoriatic	Alendronate Sodium			S	Unknown			Actavis
	Asa			S	Unknown			Not Reported
	Calcium			S	Unknown			Not Reported
	Fosinopril			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Morphine			S	Unknown			Not Reported

Arthropathy; Rash; Skin Reaction; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Synthroid	S	Unknown	Not Reported
	Tylenol	S	Unknown	Not Reported
	Tylenol	S	Unknown	Not Reported
	Vitamin D	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17420198	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543721			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Anakinra			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17420556	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543700			Female	CAN

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

					otherwise specified)					
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17420679	EXPEDITED (15-DAY)		OT	CA-BAXTER-2020BAX002873			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Disease Risk Factor; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Therapeutic Product Effect Decreased	Procytox (Cyclophosphamide) 2000mg/Vial			S	Unknown	Dosage Form Not Specified		Baxter
	Cimzia			S	Unknown	Single-Use Prefilled Syringe; Dosage Form: Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form Solution Subcutaneous		Not Reported
	Imuran			S	Unknown	Dosage Form Not Specified		Not Reported
	Plaquenil			S	Unknown	Tablets		Not Reported
	Simponi			S	Unknown	Dosage Form Solution Subcutaneous		Not Reported
	Arava			C	Unknown	Tablets		Not Reported
	Azithromycin			C	Unknown	Dosage Form Not Specified		Not Reported
	Celebrex			C	Unknown			Not Reported
	Ezetrol			C	Unknown	Tablets		Not Reported
	Methotrexate			C	Unknown	Dosage Form Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17420765	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020062981			Female	CAN

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

Drug Ineffective; Hepatic Enzyme Increased; Retinopathy	Methotrexate Sodium	S	Oral	200 Mg, Weekly	Pfizer
	Sulfasalazine	S		1500 Mg, 2x/Day	Pfizer
	Plaquenil S	S		200 Mg, 2x/Day	Not Reported
	Xeljanz Xr	C		11 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17420793	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543675		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Rheumatoid Arthritis; Sleep Disorder	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Otezla			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sirukumab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ustekinumab			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Orencia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17420910	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020060246		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neuropathy Peripheral; Retinopathy	Methotrexate Sodium			S	Oral	20 Mg Weekly		Pfizer
	Hydroxychloroquine			S		400 Mg, Daily		Not Reported
	Leflunomide			S		10 Mg, Daily		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Monthly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17421152	EXPEDITED (15-DAY)		OT	NVSC2020US039748		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Hypertrophic Cardiomyopathy; Thrombocytopenia; Ventricular Hypertrophy	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Novartis
	Metoprolol			C	Unknown			Not Reported
	Losartan			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17421587	EXPEDITED (15-DAY)		OT	CA-ROCHE-2547897		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Hepatic Enzyme Abnormal; Pneumonia; Rheumatoid Arthritis; Vomiting	Rituxan			S	Intravenous drip			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Salazopyrina	S	Unknown	Not Reported
	Align	C	Unknown	Not Reported
	Loperamide	C	Oral	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17421821	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543659			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Joint Swelling; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	365.0		Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	19.0 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	2.0 Years		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine		S	Unknown	2.0 Years	Not Reported
	Lyrica		C	Oral		Not Reported
	Prednisone		C	Oral		Not Reported
	Xeljanz		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17422215	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-04546		34 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17422354	EXPEDITED (15-DAY)		OT	CA-ROCHE-2549749		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17422367	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009280			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Orencia			S	Unknown			Bristol Myers Squibb
	Etanercept			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17428134	DIRECT	Y	OT				Prefer not to disclose	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Hydroxychloroquine Generic Manufactured By Zydus Pharmaceutical			S	Oral			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2020	12770694	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076721		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Asthenia; C-Reactive Protein Increased; Cataract; Constipation; Drug Ineffective; Fatigue; Hepatic Cirrhosis; Herpes	Orencia			S	Intravenous (not otherwise specified)	10 Milligram/Kilogram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported

Zoster; Joint Injury; Loss Of Personal Independence In Daily Activities; Off Label Use; Rheumatoid Arthritis	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Bid	Not Reported
	Celecoxib	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Prednisone	C	Unknown	2 Milligram, Qd	Not Reported
	Hydromorphone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2020	15346014	EXPEDITED (15-DAY)		OT	CA-ROCHE-2178067		60 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2020	17422660	EXPEDITED (15-DAY)		DE	CA-AUROBINDO-AUR-APL-2020-007472		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Alendronic Acid			S	Unknown	70 Milligram, 1 Every 1 Week		Aurobindo
	Metformin			S	Unknown	500 Milligram, Two Times A Day		Aurobindo
	Flovent			S	Unknown	Unk		Not Reported
	Furosemide			S	Unknown	40 Milligram		Not Reported
	Ipratropium Bromide;Salbutamol			S	Unknown	Unk		Not Reported
	Lipitor			S	Unknown	10 Milligram		Not Reported
	Losec			S	Unknown	20 Milligram		Not Reported
	Nitrazadon			S	Unknown	10 Milligram		Not Reported
	Plaquenil			S	Unknown	300 Milligram, Once A Day		Not Reported
	Prednisone			S	Unknown	5 Milligram, Once A Day		Not Reported
	Salmeterol Xinafoate			S	Unknown	Unk		Not Reported
	Tylenol			S	Unknown	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	12381245	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016061262		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Multiple Allergies;	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Mycophenolate Mofetil Hydrochloride			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1.5 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

Musculoskeletal Pain; Off Label Use; Pain; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatic Disorder; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event	Gold	S	Unknown	Unk	Not Reported
	Cellcept	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Unk, Qwk	Not Reported
	Humira	S	Unknown	40 Milligram	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Apo Mycophenolate	S	Unknown	Unk	Not Reported
	Teva Mycophenolate	S	Unknown	Unk	Not Reported
	Lyrica	S	Unknown	Unk	Not Reported
	Lyrica	S	Oral	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Mycophenolate	S	Unknown	Unk	Not Reported
	Apo Hydroxyquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported

	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Prednisone	S	Unknown	25 Milligram, Qd Qd, Decrease Dose Weekly	Not Reported
	Prednisone	S	Unknown	1 Dosage Form, Qd	Not Reported
	Piroxicam	S	Unknown	Unk	Not Reported
	Pregabalin	S	Oral	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Morphine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	14634822	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-019395		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cartilage Atrophy; Drug Ineffective; Joint Swelling; Nausea; Nephrotic Syndrome; Off Label Use; Periorbital Oedema; Renal Disorder; Skin Erosion; Therapeutic Product Effect Decreased; Wrist Deformity	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Unk		Bristol Myers Squibb
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	200 Mg, Bid		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Mg, Qd		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd		Not Reported
Rituximab	S	Unknown			Not Reported
Sulfasalazine	C	Unknown	1.5 Gram, Bid		Not Reported
Leflunomide	C	Oral	10 Mg, Qd		Not Reported
Naproxen	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	15337218	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-079001			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Off Label Use; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Adalimumab			C	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	500 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Milligram		Not Reported
	Prednisone			C	Unknown	30 Milligram, Qwk		Not Reported
	Prednisone			C	Unknown	35 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Simponi	S	Subcutaneous	50 Milligram, Qmo		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Codeine	S	Unknown	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	15400433	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083739		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Off Label Use; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	15978440	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013854		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue;	Orencia			S	Unknown			Bristol Myers Squibb

Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Stress	Apo-Leflunomide	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	1 Dosage Form, Qwk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk, Q2wk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Advil [Ibuprofen]	C	Unknown		Not Reported
	Prednisone	C	Oral	6 Milligram, Qwk	Not Reported
	Prednisone	C	Oral	10 Milligram, Qd	Not Reported
	Tylenol	C	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Mefenamic Acid	C	Unknown		Not Reported
	Dequalinium Chloride	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	16387192	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-050922			Female	CAN

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

Arthralgia; Drug Ineffective; Infection; Joint Swelling; Liver Function Test Increased; Off Label Use; Pain; Paralysis; Skin Infection; Treatment Failure; Urinary Tract Infection	Orencia		S	Unknown	Unk	Bristol Myers Squibb
	Arava		S	Oral	Unk	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Xeljanz		S	Unknown	Unk	Not Reported
	Acetaminophen		C	Oral	650 Milligram	Not Reported
	Diphenhydramine		C	Oral	50 Milligram	Not Reported
	Hydroxychloroquine		C	Unknown	Unk	Not Reported
	Methylprednisolone		C	Unknown	100 Milligram	Not Reported
	Prednisone		C	Unknown	5 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	16440223	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-056344		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lymphoma; Off Label Use	Orencia			S	Unknown			Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine		S	Unknown	500 Milligram	Not Reported
	Desoximetasone		C	Unknown	10 Milligram, Qd	Not Reported
	Diclofenac		C	Unknown	100 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	16496259	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-063555			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil S			S	Unknown	Unk		Not Reported
	Plaquenil S			S	Unknown			Not Reported

Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S	Unknown			Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Unknown			Not Reported
Sulfasalazine	S	Unknown	500 Milligram		Not Reported
Sulfasalazine	S	Unknown			Not Reported
Leflunomide	S	Unknown			Not Reported
Leflunomide	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	16671604	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-077052			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Ilaris	S	Intravenous (not otherwise specified)	Unk		Not Reported
Ilaris	S	Subcutaneous	Unk		Not Reported
Leflunomide	S	Oral			Not Reported
Leflunomide	S	Unknown			Not Reported
Methotrexate	S	Intra-arterial			Not Reported
Methotrexate	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Remicade	S	Unknown			Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Rituxan	S	Unknown			Not Reported
Sulfasalazine	S	Unknown	500 Milligram		Not Reported
Sulfasalazine	S	Unknown			Not Reported
Oxyquinoline Sulfate	S	Unknown			Not Reported
Oxyquinoline Sulfate	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Apo-Leflunomide	S	Unknown			Not Reported
Apo-Leflunomide	S	Unknown			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17422875	EXPEDITED (15-DAY)		OT	FR-ROCHE-2548690		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product	Omalizumab			S	Unknown	Unk		Not Reported

Use In Unapproved Indication; Urticarial Vasculitis	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Anakinra	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17422886	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009812			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Simponi			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17422888	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009885			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17422916	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009843		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Erythema; Gastric Haemorrhage; Nephrolithiasis; Peripheral Swelling; Pneumonia; Pulmonary Fibrosis; Skin Haemorrhage; Skin Warm	Orencia			S	Unknown			Bristol Myers Squibb
	Procytox			S	Intravenous (not otherwise specified)	200 Milligram		Not Reported
	Prednisone			S	Unknown	5 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Gold			C	Unknown			Not Reported
	Levofloxacin			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Fentanyl			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17422931	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009742		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported

Abnormal	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Methotrexate	S	Unknown	25 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	5 Milligram/Kilogram	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17422932	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009819			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	20 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	20 Milligram, Bid		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported
	Prednisone			S	Oral	5 Milligram		Not Reported
	Sulfasalazine			S	Unknown	1000 Gram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17422933	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009890			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported

Decreased	Anakinra		S	Subcutaneous		Not Reported
	Arava		S	Oral		Not Reported
	Cimzia		S	Subcutaneous		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17422934	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009905		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown	500 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17422987	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-010408		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cough; Off Label Use; Pain In Extremity; Pneumonia; Product Use Issue	Abatacept			S	Intravenous (not otherwise specified)	500 Milligram, Qmo		Bristol Myers Squibb
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17423002	EXPEDITED (15-DAY)		HO	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009209			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Medication Error; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Oral	1.5 Gram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17423205	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2020-007468		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Apo-Leflunomide	S	Unknown	500 Milligram	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	360 Milligram, 1 Every 1 Month	Not Reported
	Hydroxychloroquine	S	Unknown	680 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	12 Milligram, Every Week	Not Reported
	Methotrexate	S	Oral	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram, Every Week	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	1000 Milligram, Two Times A Day	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	680 Milligram	Not Reported
	Tocilizumab	S	Unknown	360 Milligram 1 Every 1 Month	Not Reported
	Tocilizumab	S	Unknown	360 Milligram	Not Reported
	Alendronate	C	Unknown	70 Milligram, Every Week	Not Reported

Ciclosporin	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	20 Milligram		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	11203581	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015010325		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Alopecia; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Nausea; Oedema; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Vomiting	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Methotrexate Sodium			S	Subcutaneous	20 - 25 Mg, Qwk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Qd		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			S	Oral	5 Milligram		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Rituxan			S	Unknown	1 Gram, 1/2		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Simponi			S	Unknown	50 Milligram, Q4wk		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Qmo		Not Reported
	Orencia			S	Subcutaneous	150 Milligram, Qwk		Not Reported
	Orencia			S	Subcutaneous	150 Gram		Not Reported
	Orencia			S	Subcutaneous	150 Milligram, Qmo		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported

Arava	S	Oral	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Subcutaneous	Unk	Not Reported
Folic Acid	S	Unknown	500 Milligram	Not Reported
Folic Acid	S	Unknown	5 Milligram	Not Reported
Folic Acid	S	Unknown	50 Milligram	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cetirizine	S	Unknown	10 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cortisone Acetate	S	Topical	Unk	Not Reported
Naprosyn	C	Unknown	500 Milligram, Bid	Not Reported
Naprosyn	C	Unknown	50 Milligram	Not Reported
Celebrex	C	Unknown	200 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	11271826	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2015069415		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Enbrel			S	Subcutaneous	Unk		Amgen
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Aspirin			S	Oral	Unk		Not Reported
	Aspirin			S				Not Reported
	Aspirin			S				Not Reported
	Aspirin			S				Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Gold			S				Not Reported
	Gold			S				Not Reported
	Gold			S				Not Reported
	Diclofenac Potassium			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Sodium Aurothiomalate			S	Oral	Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Motrin			S	Unknown	Unk		Not Reported
	Motrin			S				Not Reported
	Motrin			S				Not Reported
	Motrin			S				Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Naprosyn			S				Not Reported
	Naprosyn			S				Not Reported
	Naprosyn			S				Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S				Not Reported
	Plaquenil			S				Not Reported
	Plaquenil			S				Not Reported
	Voltaren			S	Unknown	Unk		Not Reported

Voltaren	S			Not Reported
Voltaren	S			Not Reported
Voltaren	S			Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S			Not Reported
Methotrexate	S			Not Reported
Methotrexate	S			Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Diclofenac	S	Topical	Unk	Not Reported
Vitamin C	S	Unknown	Unk	Not Reported
Sulfamethoxazole And Trimethoprim	S	Unknown	Unk	Not Reported
Sulfamethoxazole	S	Unknown		Not Reported
Clopidogrel	S	Unknown		Not Reported
Trimethoprim	S	Unknown	Unk	Not Reported
Apo Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo Asa	S	Unknown	325 Mg, Unk	Not Reported
Apo-Sulfatrim	S	Unknown		Not Reported
Diclofenac	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Ibuprofen	S	Unknown	Unk	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid;Clopidogrel	S	Unknown	Unk	Not Reported
Sulfatrim [Sulfadiazine;Trimethoprim]	S	Unknown	Unk	Not Reported
Asa	S	Unknown	Unk	Not Reported
Gold Sodium Thiomalate	S	Unknown		Not Reported
Tramadol	C	Unknown	Unk	Not Reported

	Tramadol Hydrochloride	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	11308664	NON-EXPEDITED		OT	CA-AMGEN-CANSP2011017837		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	20 Milligram, Qwk		Amgen
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported
	Plaquenil			S	Oral	400 Milligram		Not Reported
	Apo Hydroxyquine			S	Oral	400 Milligram		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Qmo		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Qmo		Not Reported
	Apo-Leflunomide			S	Oral	10 Milligram, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	4-8mg. Kg, Monthly		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, Qmo		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	1 Dosage Form, Qmo		Not Reported

Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Qd	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
Leflunomide	S	Oral	10 Milligram, Qd	Not Reported
Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
Methotrexate	S	Intramuscular	25 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Intramuscular	25 Milligram, Qwk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Naprosyn	C	Unknown	Unk Unk, As Required	Not Reported
Ramipril	C	Unknown	Unk	Not Reported
Asa	C	Unknown	81 Milligram	Not Reported
Asa	C	Unknown	Unk	Not Reported
Metformin	C	Unknown	Unk	Not Reported
Vitamin D	C		Unk	Not Reported
Calcium	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk, As Required	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Lozide	C	Unknown	Unk	Not Reported
Lantus	C	Unknown	Unk	Not Reported
Lantus	C	Subcutaneous	Unk	Not Reported
Acetylsalicylic Acid	C	Unknown	Unk	Not Reported
Acetylsalicylic Acid	C	Unknown	81 Milligram	Not Reported
Naproxen	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Vitamin D3	C		Unk	Not Reported

	Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	11506729	EXPEDITED (15-DAY)		OT	CA-ROCHE-1632320		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Pain; Peripheral Swelling; Rheumatoid Arthritis; Skin Reaction; Skin Swelling; Swelling; Therapeutic Response Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	12215314	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016171322		73 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cardiac Failure Congestive; Diverticulitis; Drug Ineffective; Dyspnoea; Eye Disorder; Lung Disorder; Product Dispensing Error; Pulmonary Toxicity; Sensitivity To Weather Change; Therapeutic	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Milligram, Bid		Pfizer
	Sulfasalazine			S	Unknown	1 Gram, Bid		Pfizer
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer

Product Effect Incomplete	Celecoxib	S	Unknown	Unk	Pfizer
	Plaquenil	S	Unknown	1000 Milligram, Bid	Not Reported
	Plaquenil	S	Unknown	200 Milligram, 2 Every 1 Day	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	20 Mg, On Monday-Wednesday-Friday	Not Reported
	Arava	S	Unknown	10 Mg, 4x/Week	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	1 Milligram, Qd	Not Reported
	Prednisone	S		5 Milligram	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Vitamin B12	C		1200 Ug, 1 Tablet 1 Time Per Day	Not Reported
	Endocet	C		5 + 325mg 1 Tablet 2x/Day As Needed	Not Reported
	Endocet	C		1 Dose 2 Every 1 Day	Not Reported
	Indomethacin	C		Unk	Not Reported
	Pennsaid	C		Unk	Not Reported
	Oxycocet	C		2 Tablets, 4-5 Times Per Week	Not Reported
	Asa	C		325 Mg, Occasionally	Not Reported
	Naprelan	C		1000 Mg, 1-2 Times Per Month	Not Reported
	Metoprolol	C		75 Milligram, Bid	Not Reported
	Folic Acid	C		5 Mg, 3x/Week	Not Reported
	Bisoprolol	C		5 Milligram, Qd	Not Reported
	Lax-A-Day	C		Occasionally	Not Reported

Omega 3	C	12000 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	12335793	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2016054142			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	12377399	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016252940		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated;	Enbrel			S	Subcutaneous	Unk		Pfizer

Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatic Disorder; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Qwk	Unknown
	Methotrexate Sodium	S	Intra-arterial	Unk	Unknown
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Lyrica	S	Oral	Unk	Pfizer
	Lyrica	S	Unknown	Unk	Pfizer
	Sulfasalazine	S	Unknown	1.5 Mg, Bid	Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk	Not Reported
	Teva Mycophenolate	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk Solution Subcutaneous	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Cellcept	S	Unknown	Unk	Not Reported
	Cellcept	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Solution Intravenous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Powder For Solution For Intravenous	Not Reported
	Humira	S	Subcutaneous	40 Mg, Weekly	Not Reported
	Humira	S	Unknown	40 Mg, Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported

Humira	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Apo Mycophenolate	S	Unknown	Unk		Not Reported
Mycophenolate Mofetil Hydrochloride	S	Unknown	Unk		Not Reported
Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
Cimzia	S	Unknown	Unk		Not Reported
Leflunomide	S	Unknown	20 Mg, Unk		Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Mycophenolate	S	Unknown	Unk		Not Reported
Piroxicam	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	25 Mg, Qd, Decrease Dose Weekly		Not Reported
Prednisone	S		1 Dosage Form, Qd		Not Reported
Methotrexate	C		Unk		Not Reported
Morphine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	12570090	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2016092146		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Enbrel			S	Unknown	Unk		Amgen
	Celebrex			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported

	Neoral	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate Sodium	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Methotrexate	S				Not Reported
	Azathioprine	S	Unknown	Unk		Not Reported
	Celecoxib	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	12726405	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016247224		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			C		Unk		Not Reported
	Calcium			C		Unk		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Leucovorin			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	12964814	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013262		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	Unk		Apotex
	Apo-Amitriptyline			S	Unknown	Unk		Apotex
	Diclofenac Sodium			S	Unknown	Unk		Apotex
	Amitriptyline			S	Unknown	Unk		Apotex
	Apo-Diclofenac			S	Topical	Unk		Apotex
	Apo-Prednisone			S	Unknown	5 Mg, Unk		Apotex
	Elavil			S	Unknown	Unk		Apotex
	Arthrotec			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Naprosyn /00256201/			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	13237730	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-1892490		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Ill-Defined Disorder; Infection; Kidney Infection; Musculoskeletal Disorder; Rheumatoid	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Arthritis; Sepsis; Therapeutic Response Decreased	Methotrexate Sodium		S	Oral	Not Reported
	Remicade		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	13520473	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038273			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased; Off Label Use	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40.0 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	13594477	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017081646		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Psoriatic Arthropathy; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk (Single Use Prefilled Syringe)		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Q6wk		Not Reported
	Methotrexate			C	Subcutaneous	25 Milligram		Not Reported
	Inflectra			C	Intravenous (not otherwise specified)	400 Mg, (Q 0, 2, 6 Weeks, Then Every 8 Weeks)		Not Reported
	Infliximab			C	Unknown	Unk		Not Reported
	Prednisone			C	Oral	Unk		Not Reported
	Leflunomide			C		Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	13638421	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017086096		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Burning Sensation;	Enbrel			S	Unknown	Unk		Amgen

Contraindicated Product Administered; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Rituxan	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Every 10 Days	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Unknown	40 Milligram	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	50 Milligram, Q4wk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	750 Milligram, Q4wk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Adalimumab	S	Unknown	40 Milligram, 1 Every 14 Days	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Abatacept	S	Unknown	Unk	Not Reported
	Tofacitinib	S	Unknown	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported

Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	200 Milligram, Bid		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 Gram		Not Reported
Tofacitinib Citrate	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Methotrexate	C	Subcutaneous	Unk		Not Reported
Methotrexate	C	Oral	20 Milligram, Qwk		Not Reported
Methotrexate	C	Unknown	Unk		Not Reported
Methotrexate	C	Oral	Unk		Not Reported
Rabeprazole Sodium	C	Oral	20 Milligram, Qd		Not Reported
Rabeprazole Sodium	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	13915192	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017127723		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported

Arava	S	Unknown	Unk		Not Reported
Arava	S	Oral	Unk		Not Reported
Cimzia	S	Subcutaneous	200 Milligram		Not Reported
Cimzia	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Leflunomide	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
Gold	S	Unknown	Unk		Not Reported
Arthrotec	C	Unknown	Unk		Not Reported
Arthrotec	C	Oral	Unk		Not Reported
Imuran	C	Unknown	Unk		Not Reported
Vitamin D	C		Unk		Not Reported
Ergocalciferol	C	Unknown	Unk		Not Reported
Ergocalciferol	C	Unknown	Unk		Not Reported
Azathioprine	C		Unk		Not Reported
Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	14547724	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018022052		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Urinary Tract Infection	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Actemra			S	Unknown	776 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram,Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported

Methotrexate	S	Subcutaneous	25 Milligram, Qwk		Not Reported
Plaquenil	C	Unknown	400 Milligram, Qwk		Not Reported
Desoximetasone	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	5 Mg, Bid		Not Reported
Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	14556178	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018022358			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S				Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tofacitinib Citrate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported
	Tofacitinib			S	Unknown	Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	14612490	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018030916			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported

Administered; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Celebrex		S	Unknown	Unk	Not Reported
	Leflunomide		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Rituxan		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Rituximab		S	Intravenous drip	Unk	Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Xeljanz		C	Oral	5 Milligram, Bid	Not Reported
	Pantoprazole		C	Unknown	Unk Unk, Tid	Not Reported
	Loperamide		C	Oral	Unk	Not Reported
	Bifidobacterium Bifidum		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	14618306	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018031234		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Synovitis; Throat Tightness	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported

Methotrexate	S	Unknown	Unk		Not Reported
Supeudol	C	Unknown	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	14619670	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018031034		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pneumonia	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Salazopyrin			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Align			C	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Loperamide			C	Oral	2 Mg, Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Bifidobacterium Bifidum			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	15235072	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION		23 YR	Female	CAN

PHARMA-TREX2016-0429

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Oral	200 Mg 2 Tablet		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Folic Acid			C	Oral	6 Days Per Week		Not Reported
	Prednisone			C	Oral			Not Reported
	Leflunomide			C	Unknown			Not Reported

	Xeljanz	C	Oral	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Tofacitinib Citrate	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	15389696	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-082925			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Off Label Use; Rheumatoid Arthritis; Somnolence; Visual Impairment	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Mg, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2000 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd (1 Every 24 Hrs)		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid		Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Acetaminophen And Codeine Phosphate	C	Unknown	Unk		Not Reported
Meloxicam	C	Unknown	Unk		Not Reported
Synthroid	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	15707043	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018174024			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Enbrel			S	Unknown	Unk		Amgen
	Cimzia			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous drip	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Unknown	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported

	Sulfasalazine			S	Unknown	Unk			Not Reported
	Arava			S	Unknown	Unk			Not Reported
	Methotrexate			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16058160	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021169			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16201961	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019057998		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Fluctuation; Blood Pressure Increased; C-	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Enbrel			S	Subcutaneous	50 Milligram		Amgen

Reactive Protein Decreased; Colitis; Condition Aggravated; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Enbrel	S	Subcutaneous	50 Milligram	Amgen
	Enbrel	S	Subcutaneous	50 Milligram	Amgen
	Mesalazine	S	Oral	800 Milligram , 3 Every One Day	Not Reported
	Amlodipine Besylate	S	Oral	5 Milligram, Qd	Not Reported
	Amlodipine Besylate	S	Oral	Unk Unk, Qd	Not Reported
	Amlodipine Besylate	S	Unknown	Unk	Not Reported
	Asacol	S	Unknown	800 Milligram, Tid (Tablet (Enteric Coated))	Not Reported
	Diamicron	S	Unknown	Unk	Not Reported
	Gliclazide	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Acetaminophen	C	Oral	650 Milligram	Not Reported
	Atacand Plus	C	Oral	Unk, Qd	Not Reported
	Bisoprolol Fumarate	C	Oral	2.5 Milligram	Not Reported
	Crestor	C		Unk	Not Reported
	Depo-Medrol	C	Intra-articular	120.0 Milligram	Not Reported
	Depo-Medrol	C	Intramuscular	120.0 Milligram	Not Reported
	Diphenhydramine	C	Oral	50 Milligram	Not Reported
	Ebastine	C		Unk	Not Reported
	Ferrous Gluconate	C	Oral	300 Milligram	Not Reported

Folic Acid	C	Oral	5 Milligram		Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram		Not Reported
Tylenol [Paracetamol]	C		500 Milligram		Not Reported
Vitamin D3	C		1000 International Unit, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16342037	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-028219		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Gabapentin			S	Oral	100 Milligram 1 Every 2 Weeks		Aurobindo
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, 1 Every 1 Month		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram Once In A Week		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	1 Dosage Form Once In A Week		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Every Week		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, 1 Every 3 Week		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligramn Once In A Month		Not Reported
	Oxycontin			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Once A Day		Not Reported
	Sulfasalazine			S	Oral	2.5 Milligram, Once A Day		Not Reported
	Sulfasalazine			S	Oral	2.5 Gram, Once A Day		Not Reported
	Aclasta			C	Intravenous (not otherwise specified)	488 Milligram, 1 Every Month		Not Reported
	Docosahexanoic			C	Unknown	Unk, 1 Every 2 Weeks		Not Reported

Acid;Eicosapentaenoic Acid					
Nasonex		C	Unknown	Unk, Two Times A Day	Not Reported
Prednisone		C	Unknown	Unk	Not Reported
Prednisone		C	Unknown	5 Milligram, Once A Day	Not Reported
Trazodone		C	Unknown	Unk	Not Reported
Tylenol		C	Unknown	Unk	Not Reported
Tylenol		C	Oral	1000 Gigabecquerel, Once A Day	Not Reported
Tylenol		C	Oral	1000 Milligram, Once A Day	Not Reported
Trazodone Hydrochloride		C	Oral	50 Milligram	Not Reported
Zoledronic Acid		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16451229	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019260752			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Joint Swelling; Rheumatoid Arthritis; Synovitis; X-Ray Abnormal	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	50 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S		Unk		Unknown
	Sulfasalazine			S	Unknown	1 Gram, Bid		Pfizer
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

Simponi	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd		Not Reported
Xeljanz	C		11 Milligram, Qd		Not Reported
Xeljanz	C		5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16797403	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019147539			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16801343	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019148283		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S				Amgen
	Arava			S	Unknown	Unk		Not Reported

	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Ibuprofen		C		400 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16805094	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019147544			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16807517	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019148110			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Asthma; Breast Disorder; Bronchiectasis; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Fatigue; Gastrooesophageal Reflux Disease; Headache; Hypertension; Hypothyroidism; Mammoplasty; Mitral Valve Disease; Off Label Use; Pneumonia; Respiratory Disorder;	Enbrel			S	Unknown	Unk		Amgen
	Bactrim			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Imuran [Azathioprine Sodium]			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Azathioprine Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

Rheumatoid Arthritis;
Rheumatoid Nodule

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16839489	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2019155407			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Alopecia	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Cimzia			C		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16843338	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019155462			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatotoxicity; Liver Function Test Increased	Enbrel			S	Unknown	Unk		Amgen
	Azathioprine			S	Unknown	150 Milligram, Qd		Not Reported
	Bromocriptine			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Colchicine			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Doxycycline			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported

	Mercaptopurine	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Methylprednisolone	S	Unknown	Unk		Not Reported
	Pamidronate Disodium	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Tenoxicam	S	Unknown	Unk		Not Reported
	Ustekinumab	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17047641	EXPEDITED (15-DAY)		DE, HO, OT	NVSC2019GR038794		57 YR	Male	GRC

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17203052	NON-EXPEDITED			US-AMGEN-USASP2019212356		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17250153	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-000432		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Pregabalin			S	Unknown	Unk		Not Reported
	Pregabalin Capsules			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Aurobindo
	Celecoxib			S	Unknown	Unk		Aurobindo
	Celecoxib Capsules			S	Unknown	Unk		Aurobindo
	Celecoxib Capsules			S				Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Allopurinol			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Perphenazine And Amitriptyline Hydrochloride			S	Unknown	Unk		Not Reported
	Perphenazine And Amitriptyline Hydrochloride			S	Unknown	Unk		Not Reported
	Apo-Amitriptyline			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Apo-Diclo			S	Unknown	Unk		Not Reported
	Apo-Diclofenac			S	Topical	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported

Celebrex	S			Not Reported
Celebrex	S	Unknown	Unk	Not Reported
Celebrex	S			Not Reported
Diclofenac	S	Unknown	Unk	Not Reported
Diclofenac	S	Unknown	Unk	Not Reported
Diclofenac Potassium	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Every Week	Not Reported
Etanercept	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Lyrica	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Parenteral	Unk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	Unk	Not Reported
Misoprostol	S	Unknown	Unk	Not Reported
Naprosyn	S	Unknown	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Nifedipine	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	750 Milligram, Every Week	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not	2000 Milligram	Not Reported

					otherwise specified)					
			Sulfasalazine		S	Unknown	Unk			Not Reported
			Winpred		S	Unknown	Unk			Not Reported
			Xeljanz		S	Oral	1 Dosage Form, Two Times A Day			Not Reported
			Tofacitinib		C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17260777	EXPEDITED (15-DAY)		DS	CA-ROCHE-2514939		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Contraindicated Product Administered; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17364151	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202001000504			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Diarrhoea; Gastroenteritis Cryptosporidial; Hypogammaglobulinaemia; Leukopenia; Neutropenia; Parasitic Gastroenteritis; Weight Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	5 Months Prior To Admission		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17423346	EXPEDITED (15-DAY)		HO	CA-ROCHE-2543760			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Therapy Non-Responder; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Benzalkonium Chloride			S	Unknown			Not Reported
	Boric Acid			S	Unknown			Not Reported
	Disodium Edetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Phenylephrine Hydrochloride			S	Unknown			Not Reported
	Rho D Immune Globulin			S	Unknown			Not Reported
	Sodium Borate			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Celebrex			C				Not Reported
	Ibuprofen			C				Not Reported
	Lipitor			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17423522	EXPEDITED (15-DAY)		OT	CA-ROCHE-2549981			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Synovitis	Rituxan			S	Unknown	Solution Intravenous		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Enbrel			C				Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17423991	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3270965-00		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Erythema; Gastric Haemorrhage; Nephrolithiasis; Peripheral Swelling; Pneumonia; Pulmonary Fibrosis; Skin Haemorrhage; Skin Warm	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Procytox			S	Intravenous (not otherwise specified)			Not Reported
	Levofloxacin			C				Not Reported
	Gold			C				Not Reported
	Fentanyl			C				Not Reported
	Codeine			C				Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17423994	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183910		55 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17423995	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184032			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Simponi	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17423996	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184178			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hepatotoxicity; Nausea; Therapeutic Response Decreased; Transaminases Increased	Leflunomide			S	Oral	10 Milligram Daily;		Barr
	Methotrexate			S	Unknown	3.5714 Milligram Daily;		Barr
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Levothyroxine Sodium			S	Oral	.075 Microgram Daily;		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Azathioprine			C	Unknown	50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17423999	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2020-CA-1183925			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Leflunomide			S	Oral			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Intra-arterial			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Anakinra	S	Unknown	Not Reported
Anakinra	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
Ilaris Single-Use Vial	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Oxyquinoline Sulfate	S	Unknown	Not Reported
Oxyquinoline Sulfate	S	Urethral	Not Reported
Remicade	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424021	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184242			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Cough; Diarrhoea; Eye Pruritus; Headache; Hepatitis; Nausea; Unevaluable Event; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Baricitinib			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424030	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1184268		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Off Label Use; Osteoporosis; Pain; Rash; Synovitis	Leflunomide			S	Unknown			Barr
	Naproxen			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424032	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184252		69 YR	Female	CAN

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

Drug Ineffective; Drug Intolerance	Leflunomide	S	Unknown	Barr
	Methotrexate	S	Unknown	Barr
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424034	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1184199		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Necrosis; Skin Ulcer	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Methotrexate			S				Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Codeine			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	2000 Milligram Daily;	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424035	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184224		71 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Leflunomide			S	Unknown			Barr
	Adalimumab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424036	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184223		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis; Diarrhoea; Gastrointestinal Disorder; Malaise	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424037	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184265			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Deformity; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Barr
	Naproxen	C	Unknown	500 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424056	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184287		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Laboratory Test Abnormal	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			C				Not Reported
	Hyzaar			C				Not Reported
	Venlafaxine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424130	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0860		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Balance Disorder; Cardiac Disorder; Coronary Artery Bypass; Dermatitis Allergic; Drug Hypersensitivity; Foot Deformity; Hand Deformity; Infection; Irritable Bowel Syndrome; Lung Neoplasm Malignant; Pain In Extremity; Surgery; Therapeutic Product Effect Decreased; Toe Amputation	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Asa			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Arnica Montana			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424323	EXPEDITED (15-DAY)		OT	CA-ROCHE-2548729		67 YR	Female	CAN

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

	Atorvastatin		C	Unknown	Not Reported
	Pantoloc [Pantoprazole]		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424363	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543625			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single Use		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	5.0 Years		Not Reported
	Humira			S	Subcutaneous	9.0 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	15.0 Years		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424372	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543685		67 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424379	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184207		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled			S	Subcutaneous			Not Reported

	Syringe				
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424381	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184258			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Vomiting	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Orencia			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424446	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543666		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

Acetaminophen	C			Not Reported
Arava	C	Unknown		Not Reported
Calcium Carbonate	C			Not Reported
Cymbalta	C			Not Reported
Elavil [Amitriptyline Hydrochloride]	C	Unknown		Not Reported
Hydrochlorothiazide	C	Unknown		Not Reported
Imitrex [Sumatriptan]	C			Not Reported
Lyrica	C	Unknown		Not Reported
Premarin	C			Not Reported
Sumatriptan Succinate	C			Not Reported
Tenormin	C			Not Reported
Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424450	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184333		81 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Condition Aggravated; Drug Ineffective; Pain; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Celebrex			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424451	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183903		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropod Sting; Drug Hypersensitivity; Drug Ineffective; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Codeine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424479	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0886			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Overdose; Retinopathy	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Xeljanz Xr			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424513	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0882		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neuropathy Peripheral; Retinopathy	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424557	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184300			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Impaired Work Ability; Pain; Rheumatoid Arthritis; Swelling	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424586	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184311		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Drug Ineffective; Foot Deformity; Gait Disturbance; Gastric Disorder	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	1 Every 1 Week		Barr
	Naproxen			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424587	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184310		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Tuberculin Test Positive	Leflunomide			S	Oral	10 Mg		Barr
	Methotrexate			S	Unknown	5 Mg		Barr
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424589	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184306			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	20 Mg, 1 Every 1 Week		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Bupropion			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424592	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184274		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Leflunomide			S	Oral	5 Mg		Barr
	Methotrexate			S	Unknown	5 Mg		Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424593	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184285		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Inflammation; Insomnia; Nodule; Pain In Extremity; Pollakiuria; Rheumatoid Arthritis	Leflunomide			S	Unknown	10 Mg		Barr
	Leflunomide			S	Unknown	20 Mg		Barr
	Methotrexate			S	Subcutaneous	1 Every 1 Week		Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424594	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184312			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Ineffective; Drug Intolerance; Feeding Disorder; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Leflunomide			S	Unknown	20 Mg		Barr
	Methotrexate			S	Subcutaneous	20 Mg, 1 Every 1 Week		Barr
	Methotrexate			S	Subcutaneous	25 Mg, 1 Every 1 Week		Barr
	Varenicline Tartrate			S	Oral	1 Dosage Forms Daily;		Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Acetaminophen	C			Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown		Not Reported
Naproxen	C	Unknown		Not Reported
Oxycodone Hydrochloride	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Rosuvastatin Calcium	C	Unknown		Not Reported
Tofacitinib Citrate	C	Unknown		Not Reported
Valtrex	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424595	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184271			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Retinopathy	Leflunomide			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424596	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184317		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Liver Injury; Loss Of Personal Independence In Daily Activities; Neck Pain; Nodule; Pain; Pain In	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Extremity; Swelling	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424856	EXPEDITED (15-DAY)		HO	CA-ROCHE-2551552			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424985	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0830		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Anakinra			S	Unknown	100mg		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Celecoxib			S	Unknown			Not Reported
	Celecoxib			S				Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported

	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17425593	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542835		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17425921	EXPEDITED (15-DAY)		CA, HO	CA-ROCHE-2543640			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anaemia Of Chronic Disease; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Haemodilution; Headache; Hepatic Cyst; Hepatic Haematoma; Interferon Gamma Release Assay Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Musculoskeletal Stiffness; Neutropenia; Pulmonary Fibrosis; Pulmonary Mass; Pyrexia; Renal Cyst; Thalassaemia	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Isoniazid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17425932	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543671		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17426308	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020066855			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspepsia; Food Intolerance; Hepatotoxicity; Rash; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Azathioprine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Imuran [Azathioprine Sodium]			C		Unk		Not Reported
	Methotrexate			C		1 Every 24 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17426433	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1184330		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy;	Alendronate Sodium			S	Oral			Actavis
	Leflunomide			S	Oral			Barr
	Prednisone			S	Oral			Actavis

Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Pregnancy; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Prednisone	S	Oral		Actavis
	Actemra	S	Subcutaneous		Not Reported
	Arava	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Diclofenac	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram Daily;	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral	20 Milligram Daily;	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram Daily;	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not		Not Reported

			otherwise specified)		
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral	2000 Milligram Daily;	Not Reported
	Sulfathalidine	S	Oral		Not Reported
	Sulfathalidine	S	Oral	2000 Milligram Daily;	Not Reported
	Tofacitinib	S	Unknown	10 Milligram Daily;	Not Reported
	Tofacitinib Citrate	S	Unknown	10 Milligram Daily;	Not Reported
	Topicort	S	Cutaneous		Not Reported
	Salazopyrin	C	Unknown		Not Reported
	Atasol [Paracetamol]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17426935	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011175			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17427012	EXPEDITED (15-DAY)		HO	CA-ROCHE-2542851		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Myochrysine	S	Parenteral	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17427045	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183889		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Joint Swelling; Off Label Use; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Amitriptyline Hydrochloride			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

Calcium Carbonate	C	Unknown		Not Reported
Cymbalta	C	Unknown		Not Reported
Elavil [Amitriptyline Hydrochloride]	C	Unknown		Not Reported
Hydrochlorothiazide	C	Unknown		Not Reported
Lyrica	C	Unknown		Not Reported
Premarin	C	Unknown		Not Reported
Sumatriptan Succinate	C	Unknown		Not Reported
Tenormin	C	Unknown		Not Reported
Tofacitinib	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17427052	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1184155		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal;	Leflunomide			S	Unknown	1 Dosage Forms Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Aclasta			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Rheumatoid Arthritis; Sleep Disorder; Spinal Stenosis; Treatment Failure	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Plaquenil	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Tramacet	S	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Lorazepam	C	Unknown	1 Milligram Daily;	Not Reported
	Lyrica	C	Oral	300 Milligram Daily;	Not Reported
	Metformin	C	Unknown	1000 Milligram Daily;	Not Reported
	Metformin	C	Unknown	5 Milligram Daily;	Not Reported
	Methylprednisolone Acetate	C	Intramuscular		Not Reported
	Methylprednisolone Acetate	C	Subcutaneous		Not Reported
	Methylprednisolone Acetate	C	Intramuscular		Not Reported
	Methylprednisolone Acetate	C	Subcutaneous		Not Reported
	Nortriptyline Hydrochloride	C			Not Reported
	Nortriptyline Hydrochloride	C			Not Reported
	Nortriptyline Hydrochloride	C	Unknown	20 Milligram Daily;	Not Reported
	Premarin	C	Unknown		Not Reported
	Risedronate Sodium	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported
	Vagifem	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17427779	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183906			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Leflunomide			S	Oral			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported

	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17427788	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1184415		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abscess; Adrenal Insufficiency; Alanine Aminotransferase Increased; Ascites; Asthenia; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Potassium Decreased; Blood Pressure Diastolic Abnormal; Blood Pressure Increased; Congestive Hepatopathy; Depression; Diverticulitis; Endometrial Disorder; Enterococcus Test Positive; Fibrosis; Gamma-Glutamyltransferase Increased; Gastrointestinal Disorder; Generalised Oedema; Heart Rate Increased; Herpes Zoster; Hypersensitivity;	Rosuvastatin			S	Unknown			Teva
	Piperacillin/Tazobactam			S	Unknown			Not Reported
	Prednisone			S	Unknown	10 Milligram Daily;		Actavis
	Mycophenolate Mofetil			S	Unknown	1000 Milligram Daily;		Teva
	Furosemide			S	Unknown			Ivax
	Ceftazidime			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Vancomycin Hydrochloride			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Actonel			C				Not Reported
	Apo-Amiodarone Tablets			C				Not Reported
	Apo-Ketorolac			C				Not Reported
	Diphenhydramine			C				Not Reported
	Eprex Sterile Solution			C				Not Reported
	Escitalopram			C				Not Reported
	Humalog			C				Not Reported
	Hydrochlorothiazide			C				Not Reported

Hypoglycaemia; Hypotension; Increased Appetite; Influenza; Infusion Related Reaction; Injection Site Extravasation; Intensive Care Unit Acquired Weakness; Intervertebral Disc Protrusion; Joint Effusion; Joint Swelling; Micturition Disorder; Myelopathy; Myopathy; Nasopharyngitis; Nausea; Nerve Compression; Neuropathy Peripheral; Neutropenia; Osteoarthritis; Pancytopenia; Peripheral Sensorimotor Neuropathy; Peritonitis; Pneumonia; Pseudomonal Bacteraemia; Rheumatoid Arthritis; Septic Shock; Therapeutic Response Decreased; Vomiting; Weight Decreased; Weight Increased	Hydroxychloroquine	C	Not Reported
	Januvia	C	Not Reported
	Metformin	C	Not Reported
	Methylprednisolone Nos	C	Not Reported
	Metoprolol	C	Not Reported
	Pantoloc /01263204/	C	Not Reported
	Pantoprazole	C	Not Reported
	Potassium Chloride	C	Not Reported
	Risedronate	C	Not Reported
	Slow-K Tab	C	Not Reported
	Tylenol	C	Not Reported
	Ventolin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17427953	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184412			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Pain	Rosuvastatin			S	Unknown			Actavis
	Piperacillin/Tazobactam			S	Unknown			Not Reported
	Prednisone			S	Unknown	10 Milligram Daily;		Actavis
	Ceftazidime			S	Unknown			Not Reported
	Cellcept			S	Unknown	1000 Milligram Daily;		Not Reported
	Lasix			S	Unknown			Not Reported

	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Vancomycin	S	Unknown		Not Reported
	Acetaminophen	C			Not Reported
	Actonel	C			Not Reported
	Apo-Amiodarone Tablets	C			Not Reported
	Diphenhydramine	C			Not Reported
	Eprex Sterile Solution	C			Not Reported
	Escitalopram	C			Not Reported
	Hydrochloroquine	C			Not Reported
	Hydrochlorothiazide	C			Not Reported
	Insulin Lispro	C			Not Reported
	Januvia	C			Not Reported
	Metformin	C			Not Reported
	Methylprednisolone Nos	C			Not Reported
	Metoprolol	C			Not Reported
	Pantoloc	C			Not Reported
	Pantoprazole	C			Not Reported
	Potassium Chloride (Kcl Reatrd)	C			Not Reported
	Risedronate Sodium	C			Not Reported
	Slow-K Tab	C			Not Reported
	Tylenol	C			Not Reported
	Ventolin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17427971	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184685			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Pneumonitis; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Pneumococcal Vaccine Polysacch 23v	C	Unknown	Not Reported
	Prevnar 13	C	Unknown	Not Reported
	Varicella Zoster Vaccine Live	C	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17428024	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1184585		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Ineffective; Fatigue; Loose Body In Joint; Off Label Use; Osteoporotic Fracture; Pain; Synovitis	Leflunomide			S	Unknown	2 Dosage Forms Daily;		Barr
	Naproxen			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17428042	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184562		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Neoral		S	Unknown		Not Reported
	Rapamune		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Tacrolimus		S	Oral	6 Milligram Daily;	Not Reported
	Tacrolimus		S	Oral	4 Milligram Daily;	Not Reported
	Azathioprine		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17428069	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184867		53 YR	Female	CAN

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

Sulfasalazine	S	Unknown			Not Reported
Acetaminophen	C	Unknown			Not Reported
Advil [Ibuprofen]	C	Unknown			Not Reported
Prednisone	C	Oral	6 Milligram Daily;		Not Reported
Prednisone	C	Oral	10 Milligram Daily;		Not Reported
Mefenamic Acid	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17428628	EXPEDITED (15-DAY)		DE, OT	IN-FRESENIUS KABI-FK202001491		41 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acinetobacter Infection; Brain Abscess; Nocardiosis; Shunt Infection	Methotrexate (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Prednisolone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17428727	EXPEDITED (15-DAY)		OT	CA-ASSERTIO THERAPEUTICS, INC.-CA-2020DEP000090			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Back Pain; Drug Ineffective; Enthesopathy; Hla Marker Study Positive; Pancytopenia; Spinal Pain; Spondyloarthropathy; Synovial Disorder	Diclofenac Potassium			S	Unknown	150 Mg, Qd		Assertio Therapeutics
	Methotrexate			S	Unknown	25 Mg, Every Week		Not Reported
	Naproxen			S	Unknown	1000 Mg, Qd		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	2 G, Qd		Not Reported
	Hydroxychloroquine			C		400 Mg, Qd		Not Reported
	Leflunomide			C		Unk		Not Reported
	Piroxicam			C		20 Mg, Bid		Not Reported
	Prednisone			C		20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	11800207	NON-EXPEDITED		OT	CA-AMGEN-KDL279454		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Enbrel			S	Subcutaneous	Unk Unk, Qwk		Amgen
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Advil			C	Unknown	Unk		Not Reported
	Tylenol			C	Unknown	Unk		Not Reported
	Mefenamic Acid			C	Unknown	Unk		Not Reported

	Prednisone	C	Oral	10 Milligram, Qd		Not Reported
	Prednisone	C	Oral	6 Milligram, Qd		Not Reported
	Dequalinium Chloride	C		Unk		Not Reported
	Acetaminophen	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	12103915	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016021127		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Hip Arthroplasty; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Etanercept			S	Unknown	Unk		Amgen
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	10 Milligram		Not Reported
	Arava			C		Unk		Not Reported
	Sodium Aurothiomalate			C		Unk		Not Reported

	Xeljanz		C	Unknown	Unk	Not Reported
	Xeljanz		C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	12584285	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016355320		60 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	13413043	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017051637		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Drug Ineffective; Foot Deformity; Hepatotoxicity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass Excision;	Enbrel			S	Subcutaneous	25 Milligram, Bid		Amgen
	Methotrexate			S	Oral	22.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	17.5 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

Off Label Use; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Erythromycin		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine		S	Unknown	200 Milligram, Bid	Not Reported
	Xeljanz		S	Oral	5 Milligram, Bid	Not Reported
	Orencia		S	Unknown	1000 Milligram	Not Reported
	Leflunomide		C	Oral	20 Mg, Qd	Not Reported
	Celebrex		C		200 Mg, Bid	Not Reported
	Wellbutrin		C		300 Mg, Qd	Not Reported
	Vitamin D		C		4000 Iu, Qd	Not Reported
	Risedronate		C	Oral	35 Mg, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	14627389	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018099589			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Celebrex			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Pantoprazole			C	Unknown	Unk Unk, Tid		Not Reported

	Loperamide	C	Oral	Unk		Not Reported
	Bifidobacterium Bifidum	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	14749800	EXPEDITED (15-DAY)		HO	CA-ROCHE-2103364			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	14750039	EXPEDITED (15-DAY)		HO	CA-ROCHE-2103271			Male	CAN

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

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	14823767	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018055160			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	14921647	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044755			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Eye Disorder; Hand Deformity; Infection; Lung Disorder; Musculoskeletal Pain; Off	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

Label Use; Peripheral Swelling; Pulmonary Hypertension	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]		S	Unknown		Not Reported
	Tylenol		C	Unknown	8 Hour	Not Reported
	Acetaminophen		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	15313643	EXPEDITED (15-DAY)		HO, OT	GB-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-027152		27 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Adverse Event; Cough; Infection; Lower Respiratory Tract Infection; Malaise; Rash; Sinus Operation; Sinusitis; Swelling	Abatacept			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	15635020	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105499		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Synovitis; Treatment Failure	Orencia			S	Unknown	750 Mg, Unk		Bristol Myers Squibb
	Actemra			S	Unknown	8.0 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20.0 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	15661545	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018075758			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S				Pfizer
	Tofacitinib Citrate			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Qwk (1 Every 1 Week(S))		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	15715431	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018510528			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Cimzia			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

	Otezla			S	Unknown	Unk			Not Reported
	Otezla			S	Oral	Unk			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk			Not Reported
	Remicade			S	Unknown	Unk			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Simponi			S	Unknown	Unk			Not Reported
	Simponi			S	Subcutaneous	Unk			Not Reported
	Stelara			S	Unknown	Unk			Not Reported
	Stelara			S	Subcutaneous	Unk			Not Reported
	Arava			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	15953498	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-012379		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown	0.8 Ml, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	16075711	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013166			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Meloxicam			S	Oral	7.5 Milligram		Aurobindo
	Actemra			S	Subcutaneous	Unk, Every Week		Not Reported
	Arava			S	Unknown	20 Milligram, Once A Day		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Every Week		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Every Week		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Mobicox			S	Oral	7.5 Milligram, Once A Day		Not Reported
	Sulfasalazine			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	16284954	NON-EXPEDITED		OT	CA-AMGEN-CANSP2014093565		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Cough; Drug Ineffective; Headache; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Viral Infection	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported

	Xeljanz	S	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	16721389	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-079076			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	567 Milligram, Qmo		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Milligram, Bid		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	16819168	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019399007			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	16850473	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019412222			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Alopecia	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cimzia			C		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	16865776	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201909000777			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Cardiac Failure; Cardiotoxicity; Dyspnoea Exertional; Hypertrophic Cardiomyopathy; Palpitations; Pulmonary Hypertension; Ventricular Hypertrophy	Hydroxychloroquine			S	Unknown	300 Mg, Qd (For More Than 20 Years)		Concordia
	Metoprolol			C		Unk		Not Reported
	Losartan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	16938096	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017005654		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Ineffective; Drug Intolerance; Feeding Disorder; Hypersensitivity;	Enbrel			S		50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Unknown

Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Methotrexate Sodium	S	Subcutaneous	20 Mg, Weekly	Unknown
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Weekly	Unknown
	Sulfasalazine	S		Unk	Pfizer
	Varenicline Tartrate	S	Oral	Unk Unk, 1x/Day (Qd)	Pfizer
	Varenicline Tartrate	S	Oral	1 Df, 1x/Day	Pfizer
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Rituxan	S		Unk	Not Reported
	Cimzia	S	Subcutaneous	200 Mg, Cyclic (Other Weeks)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		400 Mg, Unk	Not Reported
	Leflunomide	S		20 Mg, Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Mg, Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Tofacitinib Citrate	C		Unk	Not Reported
	Valtrex	C		Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Rosuvastatin Calcium	C		Unk	Not Reported
	Esomeprazole Magnesium/Naproxen	C		Unk	Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C		Unk	Not Reported
	Acetaminophen	C		Unk	Not Reported
	Oxycodone Hydrochloride	C		Unk	Not Reported
	Naproxen	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17333941	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-004127			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17407715	EXPEDITED (15-DAY)		HO, OT	NVSC2020DK037178		71 YR	Female	DNK

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17425380	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-010671			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported

Consciousness; Mobility Decreased; Off Label Use	Anakinra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Unknown	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Simponi	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17425391	EXPEDITED (15-DAY)		OT	DE-ADVANZ PHARMA-202002000759			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage	Hydroxychloroquine			S	Unknown	1 Dosage Form, Qd, Film Coated Tablet		Concordia
	Eliquis			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17425627	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-010683		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	2 Every One Week		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Methotrexate	S	Unknown	20 Milligram	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	200 Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Wellbutrin	C	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17425784	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543668		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S				Not Reported
	Fosamax			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Diclofenac	C	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17425878	EXPEDITED (15-DAY)		OT	CA-SA-2020SA030850			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Intolerance; Eye Disorder; Lung Disorder; Macular Degeneration	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17425951	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184854			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Lung Disorder; Platelet Count Decreased; Rheumatoid Arthritis; Septic Shock; White Blood Cell Count Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	20 Mg		Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Tofacitinib			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17425952	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184569			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17425975	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1184657		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand	Leflunomide			S	Unknown	20 Milligram Daily;		Barr

Deformity; Mobility Decreased; Off Label Use; Pain; Product Use Issue; Swelling	Methotrexate	S	Subcutaneous	20 Mg, 1 Every 1 Week		Barr
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
	Methotrexate	S	Oral			Not Reported
	Sulfasalazine	S	Oral	3000 Milligram Daily;		Not Reported
	Acetaminophen/Oxycodone Hydrochloride/Oxycodone Terephthalate	C				Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C				Not Reported
	Ramipril	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17426616	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184539			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Intolerance; Haematochezia; Hepatic Enzyme Increased; Joint Swelling; Muscle Spasms; Nausea; Neuropathy Peripheral; Rash; Skin Burning Sensation	Leflunomide			S	Unknown			Barr
	Atorvastatin			S	Oral	40 Milligram Daily;		Teva
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Asa Ec			C	Oral	81 Milligram Daily;		Not Reported
	Folic Acid			C	Oral			Not Reported
	Vitamin D3			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17426843	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184864			Female	CAN

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

Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Leflunomide		S	Unknown	Barr
	Methotrexate		S	Unknown	Barr
	Actemra		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17426861	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184581		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Intolerance; Drug Resistance; Hip Arthroplasty; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17427313	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2020-		74 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Aphasia; Bradykinesia; Confusional State; Disease Progression; Gait Disturbance; Generalised Tonic-Clonic Seizure; Hemiparesis; Hypoaesthesia; Meningitis Noninfective; Mental Status Changes; Muscle Rigidity; Neurological Symptom; Parkinsonism; Postural Tremor; Resting Tremor	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17429397	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3272487-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Product	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Allopurinol			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Amitriptyline Hydrochloride W/Perphenazine			S	Unknown			Not Reported
	Apo-Amitriptyline			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Diclofenac			S	Topical			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Complaint; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Apo-Naproxen	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Diclofenac Sodium W/Misoprostol	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Celebrex	S		Not Reported
	Celecoxib	S	Unknown	Not Reported
	Celecoxib	S		Not Reported
	Diclofenac	S	Unknown	Not Reported
	Diclofenac Potassium	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Misoprostol	S	Unknown	Not Reported
	Naprosyn	S	Unknown	Not Reported
	Naproxen	S	Unknown	Not Reported
	Nifedipine	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pregabalin	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Winpred	S	Unknown	Not Reported

Utofacitinib	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17430681	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184673			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17430922	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020064146		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Fluid Retention; Hepatic Cirrhosis	Sulfasalazine			S	Unknown			Pfizer
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Escitalopram Oxalate			C				Not Reported
	Furosemide			C				Not Reported
	Pantoprazole			C				Not Reported
	Perindopril			C				Not Reported
	Prednisone			C				Not Reported
	Spironolactone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17431103	EXPEDITED (15-DAY)		LT, OT	CA-PFIZER INC-2020066727		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Blood Iron Decreased; Blood Pressure Increased; Headache; Interstitial Lung Disease; Joint Swelling; Monocyte Count Increased; Muscle Spasms; Osteoporosis; Oxygen Saturation Decreased; Red Blood Cell Count Decreased; Rheumatoid Arthritis; Walking Aid User	Sulfasalazine			S	Unknown			Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Sodium			S	Unknown			Not Reported
	Accupril			C				Not Reported
	Acetaminophen			C	Oral	650 Mg, Unk		Not Reported
	Apo-Atorvastatin			C				Not Reported
	Apo-Hydroxyquine			C				Not Reported
	Apo-Prednisone			C				Not Reported
	Apo-Zopiclone			C				Not Reported
	Diphenhydramine			C	Oral	50 Mg, Unk		Not Reported
	Gabapentin			C				Not Reported
	Lactaid			C				Not Reported
	Lactulose			C				Not Reported
	Levemir			C				Not Reported
	Methadone			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	100 Mg, Unk		Not Reported
	Nabilone			C				Not Reported
	Novorapid			C				Not Reported
	Pantoprazole			C				Not Reported
	Pms-Cetirizine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17431408	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184850		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Drug Intolerance; Synovitis;	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Throat Tightness	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Remicade	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Supeudol	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17431443	EXPEDITED (15-DAY)		DE	CA-TEVA-2020-CA-1187200		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Alendronate Sodium			S	Unknown			Actavis
	Ipratropium Bromide And Salbutamol Sulphate Inhalation Solution			S	Unknown			Teva
	Metformin			S	Unknown	1000 Milligram Daily;		Actavis
	Flovent			S	Unknown			Not Reported
	Lasix			S	Unknown			Not Reported
	Lipitor			S	Unknown			Not Reported
	Losec			S	Unknown			Not Reported
	Nitrazadon			S	Unknown			Not Reported
	Plaquenil			S	Unknown	300 Milligram Daily;		Not Reported
	Salmeterol Xinafoate			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17431642	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011673		30 YR	Female	CAN

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

Abdominal Discomfort; Arthralgia; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Synovitis; Treatment Failure	Orencia		S	Intravenous (not otherwise specified)	750 Milligram, Qmo	Bristol Myers Squibb
	Actemra		S	Intravenous (not otherwise specified)	600 Milligram, Qmo	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram	Not Reported
	Methotrexate		S	Oral	20 Milligram, Qwk	Not Reported
	Sulfasalazine		S	Unknown	1000 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17431933	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009197			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17431942	NON-EXPEDITED			NVSC2020US043346		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis

	Prednisone		S	Unknown	40 Mg, Qd	Not Reported
	Prednisone		S	Unknown	20 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17432560	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020026034		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Folic Acid			C		Unk		Not Reported
	Rabeprazole Sodium			C	Oral	20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17432570	EXPEDITED (15-DAY)		HO, OT	CA-BAXTER-2020BAX002983		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchiectasis; Disease Susceptibility; Drug Ineffective; Joint Swelling; Myocardial Infarction; Pulmonary Fibrosis; Toxicity To Various Agents; Upper Limb Fracture	Procytox (Cyclophosphamide) 2000mg/Vial			S	Unknown	Dosage Form: Not Specified		Baxter
	Arava			S	Oral	Dosage Form:Tablet		Not Reported
	Cimzia			S	Unknown	Dosage Form: Solution Subcutaneous, Singe Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Dosage Form: Not Specified		Not Reported
	Plaquenil			S	Oral	Dosage Form: Tablet		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17432595	EXPEDITED (15-DAY)		HO	CA-GLENMARK PHARMACEUTICALS-2020GMK046108			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal	Gabapentin			S	Oral	100 Mg, Unk		Glenmark
	Actemra			S	Intravenous (not otherwise specified)	488 Mg, 1 Every 1 Month		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Od		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Qw		Not Reported

Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Myochrysine	S	Intramuscular	50 Mg, 1 Every 3 Weeks; Formulation: Solution Intramuscular	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, 1 Every 1 Month	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2.5 G, Od	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Aclasta	C	Unknown	Unk; Formulation: Solution Intravenous	Not Reported
	Docosahexaenoic Acid W/Eicosapentae/06850301/	C	Unknown	Unk	Not Reported
	Nasonex	C	Unknown	Unk; Formulation: Spray, Metered Dose	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Trazodone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17432621	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011197		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Methotrexate			C	Unknown			Not Reported
	Supeudol			C	Unknown	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17432649	EXPEDITED (15-DAY)		HO, LT	CA-BAXTER-2020BAX002993		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Autoimmune Disorder; Cognitive Disorder; Cushing'S Syndrome; Headache; Infusion Related Reaction; Leukopenia; Muscular Weakness; Paralysis; Proteinuria; Psychotic Disorder; Therapeutic Response Decreased	Procytox (Cyclophosphamide) 2000mg/Vial			S	Unknown			Baxter
	Procytox (Cyclophosphamide) 2000mg/Vial			S	Intravenous (not otherwise specified)	Dosage Form: Not Specified		Baxter
	Apo-Azathioprine			S	Unknown	Dosage Form: Tablets		Not Reported
	Apo-Azathioprine			S	Unknown	Dosage Form: Tablets		Not Reported
	Apo-Azathioprine			S	Unknown	Dosage Form: Tablets		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown	Dosage Form: Not Specified		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Dosage Form: Solution Intravenous		Not Reported
	Rituxan			S				Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Diphenhydramine Hydrochloride			C	Unknown			Not Reported
	Methylprednisolone			C	Unknown			Not Reported
	Methylprednisolone Sodium Succinate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17450144	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Hydroxychloroquine			S				Not Reported
	Leucinamide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	11213498	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015060003		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Arthropathy; Asthma; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation; Injection Site Pruritus; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Pneumonia; Pruritus; Pulmonary Fibrosis; Rheumatoid Arthritis; Septic Shock; Synovitis; Treatment Failure; Urinary Tract Infection; Urosepsis	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Apo Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Salicylates Nos			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Imuran [Azathioprine]			S	Unknown	Unk		Not Reported
	Methyl Salicylate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Prednisone			C	Unknown	5 Milligram, Every 24 Hour		Not Reported
	Prednisone			C	Unknown	10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	11713409	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2015115197		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fall; Fatigue; Femur Fracture; Hepatic Enzyme Increased; Infection; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Off Label Use; Osteoporosis; Pain; Rash; Synovitis	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Naproxen			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	2 Gram, Unk		Not Reported
	Sulfasalazine			S	Oral	5000 Milligram, Qd		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Qmo		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Milligram, Bid		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			S	Oral	5 Milligram (2 Every One Weeks)		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Milligram, Qwk		Not Reported
	Risedronate			C	Oral	35 Milligram, Qwk		Not Reported
	Naroxin			C		Unk		Not Reported

Arava	C	Oral	20 Milligram, Qd		Not Reported
Folic Acid	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	11999139	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-1704038		59 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	12021392	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016014877		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Breast Cancer; Condition Aggravated; Contraindicated Product	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S				Amgen
	Actemra			S	Unknown	Unk		Not Reported

Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Infection; Joint Swelling; Loss Of Consciousness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Actemra	S	Unknown	8 Milligram	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S			Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	25 Mg, Qd	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	750 Milligram	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qd	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qd	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
	Gold	S	Unknown	50 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Sodium Aurothiomalate	S	Parenteral	50 Milligram	Not Reported
	Meloxicam	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	12336694	NON-EXPEDITED		DS, HO, OT	CA-AMGEN-CANSP2015094586		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Arthralgia; Arthritis; Arthropathy; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Creatinine Increased; Blood Parathyroid Hormone Decreased; Blood Pressure Systolic Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Decreased Appetite; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Erythema; Fatigue; Fear Of Injection; General Physical Health Deterioration; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Insomnia; Joint Injury; Joint Swelling; Loss Of	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Amgen
	Enbrel			S	Unknown	25 Milligram		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	20 Milligram, Qd		Amgen
	Etanercept			S	Subcutaneous	Unk		Amgen
	Etanercept			S	Unknown	Unk		Amgen
	Etanercept			S				Amgen
	Sulfasalazine			S	Oral	1 Gram, Bid		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	400 Milligram		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Certolizumab Pegol			S	Subcutaneous	Unk		Not Reported
	Certolizumab Pegol			S	Unknown	Unk		Not Reported
	Ustekinumab			S	Subcutaneous	Unk		Not Reported
	Apremilast			S	Unknown	Unk		Not Reported
	Apremilast			S	Oral	30 Milligram, Bid		Not Reported
	Apremilast			S	Unknown	60 Milligram, Bid		Not Reported
	Ibuprofen			S	Oral	600 Milligram, Every 3-4 Hours Regularly		Not Reported
	Ibuprofen			S	Oral	600 Milligram, Q4h		Not Reported
	Ibuprofen			S	Oral	600 Milligram		Not Reported

Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Pain; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Abatacept	S	Unknown	Unk	Not Reported
	Golimumab	S	Subcutaneous	Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Cyclosporin	S	Unknown	Unk	Not Reported
	Cyclosporin	S	Unknown	Unk	Not Reported
	Apo-Cyclosporine	S	Unknown	Unk	Not Reported
	Apo-Ibuprofen	S	Oral	600 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira	S			Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S			Not Reported
	Otezla	S	Oral	30 Milligram, Bid	Not Reported
	Otezla	S	Unknown	Unk	Not Reported
	Otezla	S			Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Motrin	S	Oral	600 Milligram	Not Reported
	Motrin	S	Unknown	6 Df, Qd	Not Reported
	Motrin	S	Oral	600 Milligram, Qd	Not Reported
	Motrin	S	Oral	Unk, Qd	Not Reported
	Ciclosporin	S	Oral	Unk	Not Reported
	Sulfamethoxazole	S	Oral	600 Milligram	Not Reported
	Alendronate Sodium	S	Unknown	70 Milligram 4 Every One Week	Not Reported
	Methotrexate	S	Oral	Unk Unk (4.0 Dosage Forms), Qwk	Not Reported
	Methotrexate	S	Unknown	2.5 Milligram, Qwk	Not Reported

Methotrexate	S	Unknown	10 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	17.5 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Unknown	12 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Unknown	10 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Unknown	70 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	2.5 Milligram, Qmo	Not Reported
Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	7.5 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Oral	10 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, 4 Times/Wk	Not Reported
Codeine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Cosentyx	S	Unknown	Unk	Not Reported
Cosentyx	S	Subcutaneous	300 Milligram, Qmo	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported

Rituximab	S			Not Reported
Celebrex	S	Oral	200 Milligram, Bid	Not Reported
Methotrexate Sodium	C		2.5 Milligram 4 Tablets, Once A Week	Not Reported
Methotrexate Sodium	C	Oral	4.0 Dosage Form, Qwk	Not Reported
Oxycodone Hydrochloride	C	Unknown	40 Milligram	Not Reported
Oxycodone Hydrochloride	C	Unknown	10 Milligram	Not Reported
Mogadon	C	Unknown	5 Milligram	Not Reported
Febuxostat	C	Unknown	80 Milligram, Bid	Not Reported
Colchicine	C	Oral	0.6 Milligram	Not Reported
Colchicine	C	Oral	6 Milligram	Not Reported
Acide Folique	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Nitrazepam	C	Oral	Unk	Not Reported
Nitrazepam	C		50 Milligram	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported
Oxycodone	C		40 Milligram	Not Reported
Oxycodone	C		10 Milligram	Not Reported
Uloric	C	Oral	80 Milligram, Bid	Not Reported
Uloric	C	Oral	8 Milligram, Bid	Not Reported
Oxyneo	C	Unknown	40 Milligram	Not Reported
Oxyneo	C	Unknown	10 Milligram	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Naproxen	C		500 Milligram	Not Reported
Cannabis Sativa	C		Unk	Not Reported

	Actonel	C	Oral	35 Milligram, Qwk	Not Reported
	Vitamin D 3	C	Oral	2000 International Unit	Not Reported
	Risedronate Sodium	C	Oral	35 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	12598409	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2015389516		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Blood Pressure Fluctuation; Body Temperature Decreased; Bone Density Abnormal; Chills; Cough; Deafness; Decreased Appetite; Drug Ineffective; Drug Intolerance; Fatigue; Headache; Hypercholesterolaemia; Infection; Insomnia; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Oropharyngeal Pain; Pain; Pain In Extremity; Peripheral Swelling; Pyrexia; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Rosacea; Somnolence; Stress; Swelling; Therapeutic	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Lower Doses Initially & Increased Over The Yrs Around 1997		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, 1x/Day		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	25,Unk, Qd		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Sulfasalazine			S	Oral	1 G, 2x/Day: 6 Months		Pfizer
	Methylprednisolone Sodium Succinate			S	Intravenous (not otherwise specified)	100 Milligram		Pfizer
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			S	Oral	25 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	50 Milligram, Unk		Not Reported
	Prednisone			S	Oral	3 Milligram, Qd		Not Reported
	Prednisone			S	Oral	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting; Weight Increased	Acetaminophen	S	Oral	650 Milligram	Not Reported
	Indocid	S		Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg, 1x/Day, For One Year	Not Reported
	Leflunomide	S	Unknown	20 Mg, Daily (For 1 Year)	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	S	Oral	50 Milligram	Not Reported
	Ciprodex [Ciprofloxacin Lactate]	C		Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Indomethacin [Indometacin]	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	480 Milligram, Cyclical	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Mg, 1x/Day	Not Reported
	Gold (198 Au) Colloidal	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	50 Milligram, Unk	Not Reported
	Apo-Prednisone	S	Oral	3 Milligram, Qd	Not Reported
	Apo-Prednisone	S	Oral	25 Milligram, Qd	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Cimzia	S	Subcutaneous	Unk (Single Use Prefilled Syringe)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, 1x/Day	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Mg, 2x/Day	Not Reported
	Indometacin	S	Unknown	Unk	Not Reported

Simponi	S	Subcutaneous	Unk		Not Reported
Xeljanz	C	Oral	5 Mg, 2x/Day		Not Reported
Xeljanz	C	Oral	Unk, 2x/Day		Not Reported
Folic Acid Aventis	C	Oral	Unk, Weekly		Not Reported
Folic Acid Aventis	C	Oral	5 Mg, Unk		Not Reported
Cymbalta	C	Oral	30 Mg, 1x/Day (Nightly)		Not Reported
B Complex [Vitamin B Complex]	C		Unk		Not Reported
Fish Oil	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	12913352	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-037942			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Arthropathy; Breath Sounds Abnormal; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Inflammation; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Q4wk		Bristol Myers Squibb
	Orencia			S	Unknown	125 Milligram, Qwk		Bristol Myers Squibb
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Subcutaneous	162 Milligram		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	10 Milligram, Qd	Not Reported
Apo-Leflunomide	S	Intravenous (not otherwise specified)	Unk	Not Reported
Methotrexate	S	Unknown	15 Milligram	Not Reported
Methotrexate	S	Unknown	25 Unk	Not Reported
Leflunomide	S	Oral	10 Milligram, Qd	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Prednisone	C	Intracardiac	5 Milligram, Qd	Not Reported
Prednisone	C	Unknown	10 Milligram, Bid	Not Reported
Prednisone	C	Unknown	8.5 Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Simponi	C	Subcutaneous	Unk	Not Reported
Arava	C	Unknown	Unk	Not Reported
Acetylsalicylic Acid	C	Unknown	Unk	Not Reported
Actonel	C	Unknown	Unk	Not Reported
Alprazolam	C	Unknown	Unk	Not Reported
Amlodipine	C	Unknown	Unk	Not Reported
Bisoprolol Fumarate	C	Unknown	Unk	Not Reported
Celebrex	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Metformin	C	Unknown	Unk	Not Reported
Morphine Sulfate	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Paroxetine	C	Unknown	Unk	Not Reported

Risedronate	C	Unknown	Unk		Not Reported
Simvastatin	C	Unknown	Unk		Not Reported
Telmisartan	C	Unknown	Unk		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported
Esomeprazole	C	Unknown			Not Reported
Iron Sucrose	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	13139174	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2011246063		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Enbrel			S	Subcutaneous	20 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Intramuscular	25 Milligram, Qwk		Unknown
	Plaquenil			S	Oral	400 Mg, 1x/Day		Not Reported
	Plaquenil			S	Oral	400 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Qmo		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Qmo		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	4-8mg. Kg, Monthly		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, Qd		Not Reported

Actemra	S	Intravenous (not otherwise specified)	Unk, Qmo	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Qmo	Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Qd	Not Reported
Apo Hydroxyquine	S	Oral	400 Mg, Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Mg, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Naproxen Sodium	S		Unk	Not Reported
Apo-Leflunomide	S	Oral	10 Milligram, Qd	Not Reported
Ramipril	C		Unk	Not Reported
Asa Arthritis Strength Aspirin	C		81 Mg, Unk	Not Reported
Metformin	C		Unk	Not Reported
Vitamin D	C		Unk	Not Reported
Calcium	C		Unk	Not Reported
Naproxen	C		Unk	Not Reported
Prednisone	C		Unk, As Required	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Lozide	C		Unk	Not Reported
Naprosyn	C		Unk Unk, As Required	Not Reported
Acetylsalicylic Acid	C		81 Mg, Unk	Not Reported
Acetylsalicylic Acid	C		Unk	Not Reported
Lantus	C	Unknown	Unk	Not Reported
Lantus	C	Subcutaneous	Unk	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported

Vitamin D3	C		Unk		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	13775805	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017297593		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	13921718	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017376122		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Arthritis;	Enbrel			S		Dose: 730.0		Pfizer
	Enbrel			S		Dose: 731.0		Pfizer
	Enbrel			S		Dose: 4.0 Year		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Dose: 5.0 Month		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

Rheumatoid Factor Positive	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	200 Milligram	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Arthrotec	C	Unknown	Unk	Not Reported
	Arthrotec	C	Oral	Unk	Not Reported
	Gold	S		Unk	Not Reported
	Imuran	C	Unknown	Unk	Not Reported
	Vitamin D	C		Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Azathioprine	C		Unk	Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	14187136	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2017170029		64 YR	Female	CAN

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

Drug Eruption; Drug Ineffective; Fatigue; Loose Body In Joint; Off Label Use; Osteoporotic Fracture; Pain; Synovitis	Enbrel	S	Unknown	Unk		Amgen
	Actemra	S	Unknown	Unk		Not Reported
	Adalimumab	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram		Not Reported
	Leflunomide	S	Unknown	Unk, Bid		Not Reported
	Naproxen	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Naproxen Sodium	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	14226198	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015231014		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S				Pfizer
	Methotrexate Sodium			S				Pfizer
	Methotrexate Sodium			S				Pfizer
	Ibuprofen			S	Unknown	Unk		Pfizer
	Sulfamethoxazole W/Trimethoprim			S	Unknown	Unk		Not Reported
	Aspirin			S	Unknown	Unk		Not Reported
	Aspirin			S				Not Reported
	Aspirin			S				Not Reported
	Aspirin			S				Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported

Arava	S			Not Reported
Voltaren	S	Unknown	Unk	Not Reported
Voltaren	S			Not Reported
Voltaren	S			Not Reported
Voltaren	S			Not Reported
Naprosyn	S	Unknown	Unk	Not Reported
Naprosyn	S			Not Reported
Naprosyn	S			Not Reported
Naprosyn	S			Not Reported
Naprosyn	S			Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S			Not Reported
Humira	S			Not Reported
Humira	S			Not Reported
Gold	S	Unknown	Unk	Not Reported
Gold	S			Not Reported
Gold	S			Not Reported
Gold	S			Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Plaquenil	S			Not Reported
Plaquenil	S			Not Reported
Motrin	S	Unknown	Unk	Not Reported
Motrin	S			Not Reported
Motrin	S			Not Reported
Motrin	S			Not Reported
Diclofenac Potassium	S	Unknown	Unk	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Sodium Aurothiomalate	S	Oral	Unk	Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Diclofenac	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid W/Clopidogrel	S	Unknown	Unk	Not Reported

Acetylsalicylic Acid W/Clopidogrel	S			Not Reported
Acetylsalicylic Acid W/Clopidogrel	S			Not Reported
Acetylsalicylic Acid W/Clopidogrel	S			Not Reported
Vitamin C [Ascorbic Acid]	S	Unknown	Unk	Not Reported
Sulfamethoxazole	S	Unknown	Unk	Not Reported
Trimethoprim	S	Unknown	Unk	Not Reported
Apo Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo Asa	S	Unknown	325 Mg, Unk	Not Reported
Tramadol	S	Unknown	Unk	Not Reported
Tramadol Hydrochloride	S		Unk	Not Reported
Apo-Sulfatrim	S	Unknown	Unk	Not Reported
Clopidogrel	S		Unk	Not Reported
Sulfamethoxazole And Trimethoprim	S		Unk	Not Reported
Diclofenac	S		Unk	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Asa	S	Unknown	Unk	Not Reported
Sulfatrim [Sulfadiazine;Trimethoprim]	S	Unknown	Unk	Not Reported
Gold Sodium Thiomalate	S	Unknown	Unk	Not Reported
Tramadol	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	14559058	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018072306		67 YR	Female	CAN

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

Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Response Decreased; Urinary Tract Infection	Enbrel		S	Subcutaneous	50 Mg, Qwk	Pfizer
	Methotrexate Sodium		S	Subcutaneous	15 Milligram, Qwk	Pfizer
	Methotrexate Sodium		S	Subcutaneous	25 Milligram, Qwk	Pfizer
	Actemra		S	Unknown	776 Milligram	Not Reported
	Hydroxychloroquine		S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Mg, Unk	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	750 Milligram, Qmo	Not Reported
	Humira		S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		C	Unknown	400 Milligram, Qwk	Not Reported
	Xeljanz		C	Unknown	5 Mg, Bid	Not Reported
	Desoximetasone		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	14631653	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018102054		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Synovitis; Throat Tightness	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Supeudol			C	Unknown	5.0 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	14632234	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016103661		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Pfizer
	Etanercept			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly (Qwk)		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Hydroxychloroquine			S	Unknown	Unk, (Therapy Duration: 730.0)		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Unknown	10 Milligram		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported
	Arava			C		Unk		Not Reported
	Sodium Aurothiomalate			C		Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	5 Mg, 2x/Day		Not Reported

	Leflunomide			C	Unknown	Unk				Not Reported
	Remicade			C	Intravenous (not otherwise specified)	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	15558530	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018149419			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Bone Erosion; Contraindicated Product Administered; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Exostosis; Foot Deformity; Headache; Hepatic Cirrhosis; Infection; Joint Dislocation; Joint Stiffness; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Pneumonia; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Rituxan			S	Intravenous drip	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sirukumab			S	Unknown	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported

	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Morphine	S	Unknown	Unk	Not Reported
	Dilaudid	C		Unk	Not Reported
	Wellbutrin	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	15616222	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2550220-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiovascular Disorder; Menorrhagia; Surgery; Uterine Haemorrhage	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	15632466	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105344		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, Bid		Not Reported
	Prednisone			S	Oral	5 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported

	Winpred	S	Oral	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	15632602	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-110215			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Headache; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Tremor	Orencia			S	Unknown	40 Mg, Q2wk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	15 Milligram, Qwk		Not Reported
	Pantoprazole Magnesium			C	Oral	40 Mg, Qd		Not Reported
	Tenofovir Disoproxil Fumarate			C	Oral	300 Mg, Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Zopiclone			C	Unknown	7.5 Mg, Qd		Not Reported
	Folic Acid			C	Oral	2.5 Mg, Qd		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	15756331	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015044981		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Alopecia; Arthropathy; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Glossodynia; Hand Deformity; Nausea; Oedema; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Vomiting	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	Unk, Weekly		Unknown
	Methotrexate Sodium			S	Oral	25 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Bid		Pfizer
	Sulfasalazine			S	Unknown	1 Gram, Bid		Pfizer
	Celebrex			S		200 Mg, Unk		Pfizer
	Xeljanz			S	Oral	5 Milligram, Qd		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Milligram		Pfizer
	Rituxan			S	Unknown	1 G, 1/2		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Simponi			S	Unknown	50 Mg, Q4wk		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Qmo		Not Reported
	Orencia			S	Subcutaneous	150 Mg, Qwk		Not Reported
	Orencia			S	Subcutaneous	150 G, Unk		Not Reported
	Orencia			S	Subcutaneous	150 Mg, Qmo		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	500 Milligram, Bid		Not Reported
	Naprosyn			S	Unknown	50 Milligram, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported

Arava	S	Oral	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Subcutaneous	Unk	Not Reported
Folic Acid	S	Unknown	500 Milligram	Not Reported
Folic Acid	S	Unknown	5 Milligram	Not Reported
Folic Acid	S	Unknown	50 Milligram	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Fosamax	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cetirizine	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cortisone Acetate	S	Topical	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	15880461	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016097219		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer

Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Nausea; Off Label Use; Pain; Treatment Failure; Vomiting	Enbrel	S	Subcutaneous	50 Mg, Qw	Pfizer
	Methotrexate Sodium	S	Oral	20 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Oral	20 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Oral	20 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Oral	20 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Oral	20 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Oral	20 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	20 Mg, Unk	Unknown
	Methotrexate Sodium	S	Subcutaneous	20 Mg, Unk	Unknown
	Methotrexate Sodium	S	Subcutaneous	20 Mg, Unk	Unknown
	Methotrexate Sodium	S	Subcutaneous	Unk	Unknown
	Methotrexate Sodium	S	Unknown	Unk, 1x/Day	Pfizer
	Sulfasalazine	S	Oral	Unk	Pfizer
	Xeljanz	S	Oral	5 Milligram, Bid	Pfizer
	Xeljanz	S	Unknown	Unk, Qd	Pfizer
	Xeljanz	S	Oral	10 Milligram, Qd	Pfizer
	Xeljanz	S	Unknown	Unk Unk, Qd	Pfizer
	Apo-Hydroxyquine	S	Oral	Unk	Not Reported
	Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Ciclosporin	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Plaquenil S	S	Oral	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg, Unk	Not Reported

Remicade	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
Orencia	S	Subcutaneous	12.5 Mg, Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	200 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Oral	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Xeljanz Xr	C		Unk	Not Reported
Simponi	C	Subcutaneous	Unk	Not Reported
Actemra	C	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Unk	Not Reported
Actemra	C	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Unk	Not Reported

	Actemra	C	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Unk	Not Reported
	Actemra	C	Intravenous (not otherwise specified)	8 Milligram, Unk	Not Reported
	Actemra	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	15931620	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656087-00		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Diclofenac			C				Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	15934011	EXPEDITED (15-DAY)		CA, DS, OT	CA-ABBVIE-19K-028-2656831-00		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Mood Swings; Neck Deformity; Neck Mass; Pain; Rheumatoid	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported

Arthritis; Treatment Failure	Apo-Prednisone	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Indomethacin	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Cymbalta	C		Not Reported
	Folic Acid	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16199946	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019059140		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product Administration; Liver Function Test Increased; Rash; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Q2wk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Qwk		Not Reported
	Plaquenil Sulfate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Unk, Single Use Prefilled Syringe		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

Rituxan	S	Intravenous (not otherwise specified)	1 Gram		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
Simponi	C	Subcutaneous	50 Milligram, Qmo		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported
Arava	C		Unk		Not Reported
Leflunomide	C		Unk		Not Reported
Prednisone	C		Unk		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16209335	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019167731		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Fluctuation; Blood Pressure Increased; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency;	Enbrel			S	Subcutaneous	50 Mg, Unk		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Unk		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Unk		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Unk		Pfizer
	Amlodipine Besilate			S	Oral	5 Mg, 1x/Day		Pfizer
	Amlodipine Besilate			S	Oral	Unk, Daily		Pfizer
	Amlodipine Besilate			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Asacol			S	Unknown	800 Mg, 3x/Day		Not Reported
	Diamicron			S		Unk		Not Reported
	Gliclazide			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Weight Increased	Humira	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S		Unk	Not Reported
	Orencia	S		Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Mesalazine	S	Oral	800 Milligram , 3 Every One Day	Not Reported
	Acetaminophen	C	Oral	650 Mg, Unk	Not Reported
	Atacand Plus	C	Oral	Unk, Qd	Not Reported
	Bisoprolol Fumarate	C	Oral	2.5 Milligram	Not Reported
	Crestor	C		Unk	Not Reported
	Depo-Medrol	C	Intra-articular	120.0 Milligram	Not Reported
	Depo-Medrol	C	Intramuscular	120.0 Milligram	Not Reported
	Diphenhydramine	C	Oral	50 Mg, Unk	Not Reported
	Ebastine	C		Unk	Not Reported
	Ferrous Gluconate	C	Oral	300 Milligram	Not Reported
	Folic Acid	C	Oral	5 Milligram	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Mg, Unk	Not Reported
	Tylenol [Paracetamol]	C		500 Milligram	Not Reported
	Vitamin D3	C		1000 International Unit, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16216763	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-020587		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand	Ramipril			S	Oral	Unk, Once A Day		Aurobindo
	Actemra			S	Intravenous (not otherwise specified)	600 Milligram,1 Every 4 Week		Not Reported

Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica; Treatment Failure	Dorzolamide Hydrochloride;Timolol Maleate	S	Unknown	1 Dosage Form, Two Times A Day	Not Reported
	Folic Acid	S	Unknown	7 Milligram, Once A Day	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Once A Day	Not Reported
	Levothyroxine	S	Unknown	1 Dosage Form, Once A Day	Not Reported
	Levothyroxine	S	Unknown	Unk, Once A Day	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Every Week	Not Reported
	Prednisone	S	Unknown	7 Milligram, Once A Day	Not Reported
	Tylenol	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Acetaminophen	S	Unknown	Unk	Not Reported
	Cosopt	S	Unknown	Unk,1 Every 12 Hours	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
	Dorzolamide;Timolol	S	Unknown	1 Dosage Form, Two Times A Day	Not Reported
	Dorzolamide;Timolol	S	Unknown	Unk, Two Times A Day	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Acetaminophen;Codeine Phosphate	C	Unknown	Unk	Not Reported
	Acetaminophen;Caffeine	C	Unknown	Unk	Not Reported
	Tylenol No.2	C	Unknown	Unk	Not Reported
	Diphenhydramine	C	Unknown	Unk	Not Reported

Methylprednisolone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16244983	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017146531		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Drug Ineffective; Hepatotoxicity; Off Label Use	Enbrel			S	Subcutaneous	25 Milligram, Bid		Pfizer
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S		200 Mg, 2x/Day		Not Reported
	Orencia			S		1000 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16444954	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033630			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity;	Meloxicam			S	Unknown	Unk		Aurobindo
	Actemra			S	Subcutaneous	160 Milligram, Every Week		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Depo-Medrol			C	Intra-articular	80 Milligram, Once A Day		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk		Not Reported

Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16570014	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-039032		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Meloxicam			S	Unknown	Unk		Aurobindo
	Acetaminophen			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	200 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Milligram, Once A Day		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tylenol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16570242	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-038959		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Glucose Increased; Bronchitis; Drug Ineffective; Fatigue; Hypersensitivity;	Rosuvastatin			S	Unknown	Unk		Aurobindo
	Actemra			S	Intravenous (not otherwise specified)	Unk, 1 Every Four Week		Not Reported

Immunosuppression; Influenza; Insomnia; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Pain; Pain In Extremity; Rash; Therapeutic Response Decreased; Treatment Failure	Actemra	S	Intravenous (not otherwise specified)	800 Milligram, 1 Every 4 Week	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Every Week	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Humalog	C	Unknown	Unk	Not Reported
	Sertraline Hydrochloride	C	Unknown	Unk	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16622993	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-041372			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Pain; Rheumatoid Arthritis	Meloxicam			S	Unknown	Unk		Aurobindo
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16804995	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019396451			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16817877	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019399512			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Asthma; Breast Disorder; Bronchiectasis; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Fatigue; Gastrooesophageal Reflux Disease; Headache; Hypertension; Hypothyroidism; Mammoplasty; Mitral Valve Disease; Off Label Use; Pneumonia; Respiratory Disorder; Rheumatoid Arthritis; Rheumatoid Nodule	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Bactrim			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Imuran [Azathioprine Sodium]			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Azathioprine Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16824457	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019401916		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous	Enbrel			S		50 Mg, Weekly		Pfizer
	Enbrel			S				Pfizer

	Methotrexate Sodium	S	Unk	Pfizer
	Arava	S	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unk	Not Reported
	Ibuprofen	C	400 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16851776	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019414089			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatotoxicity; Liver Function Test Increased	Enbrel			S	Unknown	Unk		Pfizer
	Doxycycline Hyclate			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methylprednisolone			S	Unknown	Unk		Pfizer
	Pamidronate Disodium			S	Unknown	Unk		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Azathioprine			S	Unknown	150 Milligram, Qd		Not Reported
	Bromocriptine			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Colchicine			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Mercaptopurine			S	Unknown	Unk		Not Reported
	Tenoxicam			S	Unknown	Unk		Not Reported
	Ustekinumab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16865487	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3765		73 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cardiac Failure Congestive; Diverticulitis; Drug Ineffective; Dyspnoea; Eye Disorder; Lung Disorder; Pulmonary Toxicity; Sensitivity To Weather Change; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown	20 Mg On Monday-Wednesday-Friday		Not Reported
	Arava			S	Unknown	4 Times A Week		Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Vitamin B12			C	Unknown			Not Reported
	Endocet			C	Unknown	1 Tablet 2 Times Per Day As Needed,		Not Reported

	Indomethacin	C	Unknown		Not Reported
	Pennsaid	C	Unknown		Not Reported
	Oxycocet	C	Unknown	2 Tablets 4-5 Times Per Week	Not Reported
	Asa	C	Unknown	Occasionaly	Not Reported
	Naprelan	C	Unknown	1-2 Times	Not Reported
	Metoprolol	C	Unknown		Not Reported
	Bisoprolol	C	Unknown		Not Reported
	Lax-A-Day	C	Unknown		Not Reported
	Omega 3	C	Unknown		Not Reported
	Folic Acid	C	Unknown	3 Times/Week	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16992212	EXPEDITED (15-DAY)		OT	PT-ACCORD-159728		63 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Disease Progression; Gastrointestinal Disorder; Interstitial Lung Disease; Pulmonary Embolism	Methotrexate			S	Unknown	Unk		Accord
	Infliximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	1 G (Twice, 2 Week Apart), Cyclic(9 Cycles)		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17334288	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202001000391			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Dermatitis Exfoliative Generalised; Eczema; Rash Erythematous; Rash Maculo-Papular; Skin	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia

Exfoliation; Skin Lesion

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17359711	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1177821			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Density Abnormal; Depression; Neuropathy Peripheral	Bisoprolol			S	Unknown	12.5 Milligram Daily;		Duramed
	Calcium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Ramipril			S	Unknown	12.5 Milligram Daily;		Actavis
	Magnesium (Salt Not Specified)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Buprenorphine			S	Unknown	10 Microgram Daily;		Not Reported
	Cyanocobalamin			S	Unknown			Not Reported
	Fish Oil			S	Unknown			Not Reported
	Lasix			S	Unknown			Not Reported
	Magnesium Gluconate			S	Unknown			Not Reported
	Multivitamins			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rivaroxaban			S	Unknown	15 Milligram Daily;		Not Reported
	Vitamin B6			S	Unknown			Not Reported
	Vitamin D			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17369604	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020017394			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Feeling Abnormal; Rheumatoid Arthritis; Thirst; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	20 Milligram, 1 Every 1 Days		Not Reported

Azathioprine		S	Unknown	Unk	Not Reported
Celecoxib		S	Unknown	Unk	Not Reported
Methotrexate		S	Unknown	Unk	Not Reported
Methotrexate		S	Subcutaneous	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk	Not Reported
Xeljanz		S	Oral	5 Milligram, 1 Every 12 Hours	Not Reported
Prednisone		S	Unknown	Unk	Not Reported
Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17432990	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011159			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17432992	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-000447			Unknown	GBR

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17433116	EXPEDITED (15-DAY)		HO	CN-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-236669		41 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Phospholipidosis	Hydroxychloroquine			S	Unknown	400 Milligram, Daily		Sun
	Hydroxychloroquine			S				Sun
	Prednisone			C	Unknown	5 Mg		Not Reported
	Prednisone			C	Unknown	10 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17433216	EXPEDITED (15-DAY)		HO	CH-ROCHE-2551375		49 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Mabthera			S	Intravenous drip	2x 500 Mg		Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Zaldiar			S	Oral			Not Reported
	Cimifemin			S	Oral			Not Reported
	Pantozol [Pantoprazole Sodium Sesquihydrate]			S	Oral			Not Reported
	Prednisolon [Prednisolone]			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17433353	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552659			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17433355	EXPEDITED (15-DAY)		OT	CA-ROCHE-2547860		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Neck Surgery; Off Label Use; Spinal Column Injury; Surgical Failure; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)		
	Mobicox	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17433750	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011515		52 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17433782	EXPEDITED (15-DAY)		OT	CA-ROCHE-2551846		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Drug Intolerance; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Cimzia	S	Subcutaneous	Not Reported
	Prednisone	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Lyrica	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17433890	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US-000495			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; End Stage Renal Disease; Maculopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	300 Milligram, Qd		Ipca
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Ipca
	Prednisone			C	Unknown	Unk		Not Reported
	Mycophenolate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17434002	EXPEDITED (15-DAY)		OT	CA-ROCHE-2551543			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Zostavax		S	Subcutaneous	Powder For Suspension Subcutaneous	Not Reported
	Desoximetasone		C	Oral		Not Reported
	Xeljanz		C	Oral		Not Reported
	Diclofenac		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17434196	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-007972			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gout; Pneumonia	Metformin			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Colchicine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Januvia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17434197	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-007975			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Gout; Hypertension; Palpitations	Metformin			S	Unknown	Unk		Aurobindo
	Colchicine			S	Unknown	Unk		Not Reported
	Januvia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sumatriptan Succinate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17434810	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020071268		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Neoplasm; Injection Site Reaction; Psoriasis; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17435005	NON-EXPEDITED			NVSC2020US043433		8 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17435041	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1016772		59 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningioma	Anastrozole			S	Oral	1 Milligram, Qd		Not Reported
	Tahor			S	Oral	1 Dosage Form, Qd		Mylan
	Plaquenil /00072603/			S	Oral	400 Milligram		Mylan
	Coumadine			S	Oral	Unk		Mylan
	Kardegic			S	Oral	1 Dosage Form, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17435118	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020058496		74 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Aphasia; Bradykinesia; Confusional State; Disease Progression; Gait Disturbance; Generalised Tonic-Clonic Seizure; Hemiparesis; Hypoaesthesia; Meningitis Noninfective; Mental Status Changes; Muscle Rigidity; Neurological Symptom; Parkinsonism; Postural Tremor; Resting Tremor	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Prednisone			S		10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17435391	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2020M1018354		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Cardiac Failure; Hypertrophic Cardiomyopathy; Overdose	Hydroxychloroquine			S	Unknown	300 Milligram, Qd		Not Reported
	Metoprolol			C	Unknown	Unk		Mylan
	Losartan			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17435435	EXPEDITED (15-DAY)		DE, HO	US-MYLANLABS-2020M1018837		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Drug Ineffective; Intentional Overdose; Pulmonary Oedema; Toxicity To Various Agents	Hydroxychloroquine			S	Oral	6 G Missing		Not Reported
	Ibuprofen			S	Oral	Unk		Not Reported
	Naproxen			S	Oral			Not Reported
	Epinephrine			S	Unknown			Not Reported
	Potassium			S	Unknown	Unk		Not Reported

Norepinephrine	S	Unknown	Unk		Not Reported
Sodium Bicarbonate	S	Unknown	Drips		Mylan
Calcium	S	Unknown	Unk		Mylan
Dextrose	S	Unknown	Unk		Mylan
Vasopressin	S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17436860	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1018093		23 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Drug Interaction; Palpitations	Escitalopram			S	Oral	20 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	2 Dosage Form, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17483874	DIRECT		DS, OT			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Depression; Pain	Plaquenil	Y		S	Oral	Quantity:90 Pills;Other Frequency:2x/Day For One Mon;	3 MTH	Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	11418532	NON-EXPEDITED		OT	CA-AMGEN-CANSP2013008516		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst;	Enbrel			S	Subcutaneous	Unk		Amgen
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Certolizumab Pegol			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Not Reported

Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	1 G, Unk	Not Reported
	Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Arava	S	Unknown	20 Mg, Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Neoral	S	Unknown	Unk	Not Reported
	Prograf	S	Unknown	Unk	Not Reported
	Prograf	S	Oral	3.0 Mg, Q12h	Not Reported
	Prograf	S	Oral	2.0 Mg, Q12h	Not Reported
	Rapamune	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxyquinoline Sulfate	S	Unknown	Unk	Not Reported
	Tacrolimus	S	Unknown	3 Milligram 1 Every 12 Hours	Not Reported
	Azathioprine	C		25 Mg, Unk	Not Reported
	Imuran	C		25 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	11519456	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2015095516		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	Unk Unk, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk Unk, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qd		Not Reported

Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Injury; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Pregnancy; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Wound	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Parenteral	Unk	Not Reported
	Methotrexate	S	Oral	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Bid	Not Reported
	Sulfasalazine	S	Unknown	1500 Milligram, Bid	Not Reported
	Sulfasalazine	S	Oral	Unk, Bid	Not Reported
	Sulfasalazine	S	Subcutaneous	1 Gram, Bid	Not Reported
	Sulfasalazine	S	Unknown	1000 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Unknown	400 Milligram, Qmo	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	20 Milligram	Not Reported

Arava	S	Oral	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Plaquenil	S	Oral	400 Milligram, Qd	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	400 Milligram, Qd	Not Reported
Plaquenil	S	Subcutaneous	Unk	Not Reported
Apo-Folic Acid	S	Unknown	5 Milligram	Not Reported
Apo-Folic Acid	S	Unknown	1 Unk, Unk	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Unknown	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Fosamax	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Unknown	Unk (Intra Corpus Cavernosum)	Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown	10 Milligram	Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown	Unk	Not Reported
Topicort (Hydrocortisone Acetate)	S	Subcutaneous	Unk	Not Reported
Topicort (Hydrocortisone Acetate)	S	Other	Unk	Not Reported
Topicort (Hydrocortisone Acetate)	S	Oral	Unk	Not Reported
Topicort (Hydrocortisone Acetate)	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	25 Milligram	Not Reported
Cetirizine Hydrochloride And	S	Unknown	10 Unk	Not Reported

Pseudoephedrine Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
Cortisone Acetate	S	Oral	25 Milligram	Not Reported
Cortisone Acetate	S	Unknown	Unk (Tablet)	Not Reported
Cortisone Acetate	S	Topical	Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	25 Milligram	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Cosentyx	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	40 Milligram	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Unk	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Alendronate Sodium	S	Unknown	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Diclofenac	S	Unknown	Unk	Not Reported
Diclofenac	S	Unknown	50 Milligram	Not Reported
Paracetamol	S	Unknown	Unk	Not Reported
Cortisone	S	Unknown	Unk	Not Reported
Zyrtec [Cetirizine Hydrochloride]	S	Unknown	10 Milligram (5mg/5ml)	Not Reported
Zyrtec [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	5 Milligram	Not Reported
Folic Acid	S	Unknown	1.0 Milligram	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported

Hydroxychloroquine	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Cetirizine	S	Unknown	10 Milligram	Not Reported
Tocilizumab	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Atasol	C		Unk	Not Reported
Ibuprofen	C	Unknown	Unk	Not Reported
Lisinopril	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C		Unk	Not Reported
Prednisolone	C	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	12691303	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016051528		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Breast Cancer; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Infection; Joint Swelling; Loss Of Consciousness;	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S				Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, 1x/Day		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qd		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	8 Milligram		Not Reported

Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Arava	S	Unknown	Unk	Not Reported
	Arava	S			Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	750 Milligram	Not Reported
	Plaquenil	S		Unk	Not Reported
	Plaquenil	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
	Gold	S	Unknown	50 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Sodium Aurothiomalate	S	Parenteral	50 Milligram	Not Reported
	Meloxicam	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	12890168	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP013157		66 YR	Male	CAN

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

Abdominal Pain; Asthenia; Condition Aggravated; Diarrhoea; Dizziness; Fatigue; Hernia; Pneumonia; Rheumatoid Arthritis	Gabapentin	S	Unknown	Unk	Apotex
	Folic Acid	S	Unknown	1 Df, B.I.Wk.	Not Reported
	Prednisone	S	Unknown	5 Mg, Qd	Not Reported
	Apo-Prednisone	S	Unknown	5 Mg, Qd	Apotex
	Hydroxychloroquine	S	Unknown	200 Mg, Bid	Apotex
	Esomeprazole Magnesium Trihydrate	S	Unknown	40 Mg, Qd	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Q.I.W	Not Reported
	Nexium /01479302/	S	Unknown	40 Mg, Qd	Not Reported
	Plaquenil /00072602/	S	Unknown	200 Mg, Bid	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Oral	5 Mg, Qd	Not Reported
	Xeljanz	S	Oral	5 Mg, Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	14262244	EXPEDITED (15-DAY)		OT	BR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-108976		38 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Intentional Product Use Issue; Maternal Exposure During Pregnancy	Abatacept			S	Intravenous (not otherwise specified)	500 Mg, Qmo		Bristol Myers Squibb
	Ibuprofen			S	Unknown	Unk		Bristol Myers Squibb
	Reuquinol			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	14496561	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007222			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Off Label Use; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Orencia			S	Unknown	125 Mg, Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Tylenol 8 Hr Arthritis Pain			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	14634808	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0733			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Product Effect Decreased; Treatment Failure; Vomiting	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Loperamide	C	Unknown	Not Reported
	Bifidobacterium Bifidum	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	14638057	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-058741		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition Aggravated; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Apo-Prednisone			S	Oral	Unk Unk, Qd		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			S	Oral	20 Mg, Qd		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	500 Mg, Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
	Simponi	S	Subcutaneous	50 Milligram	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tofacitinib Citrate	S	Unknown	5 Milligram, Bid	Not Reported
	Rituxan	S	Unknown	1 G, Bid	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
	Arava	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	14639973	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0745		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Synovitis; Throat Tightness	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Supeudol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	15305086	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-074825		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Sinusitis; Vulval Abscess	Abatacept			S	Subcutaneous	125 Mg, Unk		Bristol Myers Squibb
	Aspirin			S	Unknown	Unk		Bristol Myers Squibb
	Ibuprofen			S	Unknown	Unk		Bristol Myers Squibb
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	15400274	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083691			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Hypercalcaemia; Infusion Related Reaction; Off Label Use; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Ulcer	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	360 Mg, Qmo		Not Reported
	Actemra			S	Unknown	680 Milligram, Qmo		Not Reported
	Alendronate			S	Unknown	70 Mg, Qwk		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Mg, Unk		Not Reported
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	10 Mg, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram, Bid		Not Reported

Rituxan	S	Unknown	1000 Gram, Bid		Not Reported
Apo-Leflunomide	S	Oral			Not Reported
Myochrysine	S	Parenteral	50 Milligram		Not Reported
Sulfasalazine	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported
Ciclosporin	C	Unknown	150 Mg, Qd		Not Reported
Prednisone	C	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	15574827	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018445878			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Bone Erosion; Contraindicated Product Administered; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Exostosis; Foot Deformity; Headache; Hepatic Cirrhosis; Infection; Joint Dislocation; Joint Stiffness; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Pneumonia; Synovitis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Morphine Sulfate			S	Unknown	Unk		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported

	Orencia	S	Unknown	Unk	Not Reported
	Otezla	S	Unknown	Unk	Not Reported
	Otezla	S	Oral	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous drip	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sirukumab	S	Unknown	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Dilaudid	C		Unk	Not Reported
	Wellbutrin	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	15727088	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3743			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Otezla			S	Unknown			Not Reported
	Otezla			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Unknown	Not Reported
	Stelara	S	Subcutaneous	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	15934107	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2655644-00		67 YR	Female	CAN

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

	Arthrotec	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Imuran	C	Unknown		Not Reported
	Azathioprine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	15935702	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2657574-00		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Insomnia; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Oral			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	15984048	EXPEDITED (15-DAY)		OT	DE-ABBVIE-19K-062-2667153-00			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Humira			S	Subcutaneous	Unknownj		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Unknown		Not Reported

Plaquenil	S	Oral		Not Reported
Neoral	S	Oral	Unknown	Not Reported
Neoral	S	Subcutaneous	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Ciclosporin	S	Subcutaneous	Unknown	Not Reported
Ciclosporin	S	Oral	Unknown	Not Reported
Apo-Hydroxyquine	S	Oral	Unknown	Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Methotrexate Sodium	S	Oral	20 Milligram	Not Reported
Methotrexate Sodium	S	Subcutaneous	20 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Milligram	Not Reported
Sulfasalazine	S	Oral		Not Reported
Simponi	S	Subcutaneous		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituximab	S	Oral	Unknown	Not Reported
Orencia	S	Subcutaneous	125 Mg	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
Methotrexate	S	Oral	20 Mg. Unknown	Not Reported
Methotrexate	S	Subcutaneous	20 Mg. Unknown	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Unknown	Not Reported
Xeljanz	C	Oral	Unkown	Not Reported
Xeljanz	C	Oral	10 Milligram, Qd	Not Reported
Xeljanz	C	Unknown	2 Other, Qd	Not Reported

	Xeljanz	C	Oral	5 Mg, Bid,		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	16195868	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2741761-00		60 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	16473690	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1938			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Drug	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Joint Swelling; Rheumatoid Arthritis; Synovitis; X-Ray Abnormal	Methotrexate (Trade Name Unknown)		S	Unknown	Not Reported
	Methotrexate (Trade Name Unknown)		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Cimzia		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Simponi		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	16831226	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3515			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Teva Mycophenolate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	16841691	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019164824		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product Administration; Liver Function Test Increased; Rash; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Q2wk		Pfizer
	Enbrel			S	Subcutaneous	50 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Qwk		Not Reported
	Plaquenil Sulfate			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk, Single Use Prefilled Syringe		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Simponi			C	Subcutaneous	50 Milligram, Qmo		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Arava			C		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	16859652	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019419622			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Pneumonia	Enbrel			S	Subcutaneous	Unk Unk, Qwk		Pfizer

Methotrexate Sodium	S	Intra-arterial	Unk		Pfizer
Celebrex	S	Unknown	Unk		Pfizer
Naproxen Sodium	S	Unknown	Unk		Not Reported
Arava	S	Unknown	Unk		Not Reported
Gold	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	5 Milligram		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17386166	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020053154			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Rheumatoid Arthritis; Thirst; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Celecoxib			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Milligram, 1 Every 12 Hours		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, 1 Every 1 Days		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17424245	EXPEDITED (15-DAY)		OT	CA-ROCHE-2548656		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Rituximab			S	Unknown			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Medroxyprogesterone Acetate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17438913	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-007930		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular	Meloxicam			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	160 Milligram, Every Week		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Depo-Medrol	C	Other	80 Milligram	Not Reported
	Diclofenac	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Two Times A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17439382	EXPEDITED (15-DAY)		OT	CA-ROCHE-2547099			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17439437	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-007978			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Product Use In Unapproved Indication; Thrombosis; Uterine Disorder	Metformin			S	Unknown	Unk		Aurobindo
	Metformin			S				Aurobindo
	Cymbalta			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Warfarin Sodium			S	Unknown	Unk		Not Reported
	Azathioprine			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Xarelto			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17439574	EXPEDITED (15-DAY)		HO	CH-SA-2020SA038476		49 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Arava			S	Oral	10 Mg, Qd		Sanofi
	Plaquenil			S	Oral	200 Mg, Qd		Sanofi
	Paracetamol/Tramadol Hydrochloride			S	Oral	Unk		Not Reported
	Mabthera			S	Intravenous (not otherwise specified)	2x 500 Mg Every 5 Month		Not Reported
	Cimifemin			S	Oral	13 Mg, Qd		Not Reported
	Pantozol [Pantoprazole Sodium Sesquihydrate]			S	Oral	As Necessary		Not Reported
	Prednisolon [Prednisolone]			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17439700	EXPEDITED (15-DAY)		LT, OT	GR-SUN PHARMACEUTICAL INDUSTRIES LTD-		40 YR	Female	GRC

2020R1-237341

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aorta Hypoplasia; Atrioventricular Block Second Degree; Foetal Exposure During Pregnancy; Heart Block Congenital; Intracardiac Mass; Respiratory Distress; Ventricular Septal Defect	Acetylsalicylic Acid			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Sun
	Prednisolone			S	Unknown			Taro

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17439894	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011665		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Prednisone			C	Unknown	300 Milligram, Qd		Not Reported
	Methotrexate			C	Oral	25 Milligram, Qwk		Not Reported

	Desoximetasone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17440706	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020074282		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Mg, Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Adalimumab			S	Subcutaneous	40 Mg, Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Rabeprazole Sodium			C	Oral	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17440731	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020073599			Female	CAN

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

Abdominal Pain; Cough; Diarrhoea; Eye Pruritus; Headache; Hepatitis; Nausea; Vomiting	Methotrexate Sodium		S	Subcutaneous	15 Mg, Unk	Unknown
	Sulfasalazine		S	Unknown	1 G, 1 Every 12 Hours	Pfizer
	Baricitinib		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Mg, 1x/Day	Not Reported
	Leflunomide		S	Unknown	Unk Unk, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17440835	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020071257		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Synovitis	Methotrexate Sodium			S	Subcutaneous	20 Mg, Unk		Pfizer
	Sulfasalazine			S		1000 Mg, 2x/Day		Pfizer
	Etanercept			S		Unk		Pfizer
	Hydroxychloroquine			S	Oral	300 Mg, Unk		Not Reported
	Tocilizumab			S		Unk		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17441491	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011828			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Kevzara			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Unknown	650 Milligram, Bid		Not Reported

Aluminum Acetate		C	Unknown		Not Reported
Atacand		C	Unknown		Not Reported
Ergocalciferol		C	Unknown		Not Reported
Folic Acid		C	Unknown		Not Reported
Hydrodiuril		C	Unknown		Not Reported
Neurontin		C	Unknown	600 Milligram, Tid	Not Reported
Premarin		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17441763	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3283890-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Eye Disorder; Hand Deformity; Infection; Lung Disorder; Musculoskeletal Pain; Peripheral Swelling; Pulmonary Hypertension	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17442543	EXPEDITED (15-DAY)		CA, OT	GR-ALLERGAN-2008282US			Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia Foetal; Heart Block Congenital; Pregnancy; Respiratory Distress	Prednisolone Unk			S	Transplacental	Unk		Allergan
	Acetylsalicylic Acid			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	11200640	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015202903		73 YR	Female	CAN

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

Angioedema; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation; Injection Site Pruritus; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Pneumonia; Pruritus; Pulmonary Fibrosis; Rheumatoid Arthritis; Septic Shock; Synovitis; Treatment Failure; Urinary Tract Infection; Urosepsis	Enbrel	S	Unknown	Unk	Pfizer
	Enbrel	S	Subcutaneous	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Azathioprine	S	Unknown	Unk	Not Reported
	Apo Hydroxychloroquin	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Imuran [Azathioprine]	S	Unknown	Unk	Not Reported
	Methyl Salicylate	S	Unknown	Unk	Not Reported
	Salicylates Nos	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	C	Unknown	5 Milligram, Every 24 Hour	Not Reported
	Prednisone	C		10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	11227333	EXPEDITED (15-DAY)		OT	CA-ROCHE-1524822			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Joint Destruction; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	Prior To 2010		Not Reported
	Myochrysine			S	Unknown	Before 2010		Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	11525254	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2015308388		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction;	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous	Unk Unk, Qwk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Oral	25 Mg, 1x/Day		Pfizer
	Enbrel			S	Unknown	25 Mg, Unk		Pfizer
	Enbrel			S	Unknown	25 Mg, 1x/Day		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, 1x/Day		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer

Maternal Exposure During Pregnancy; Off Label Use; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Incomplete; Wound	Xeljanz	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Oral	25 Milligram	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Oral	Unk Unk, Qd	Pfizer
	Methotrexate Sodium	S	Unknown	20 Milligram, Qd	Pfizer
	Methotrexate Sodium	S	Subcutaneous	25 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Intra-arterial	25 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Parenteral	Unk	Pfizer
	Methotrexate Sodium	S	Oral	15 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Oral	25 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Sulfasalazine	S	Oral	1 G, 2x/Day	Pfizer
	Sulfasalazine	S	Unknown	500 Mg, Unk	Pfizer
	Sulfasalazine	S	Oral	1000 Mg, 2x/Day	Pfizer
	Sulfasalazine	S	Unknown	1500 Mg, 2x/Day	Pfizer
	Sulfasalazine	S	Unknown	500 Mg, Unk	Pfizer
	Sulfasalazine	S	Oral	1000 Mg, 2x/Day	Pfizer
	Sulfasalazine	S	Unknown	1500 Mg, 2x/Day	Pfizer
	Sulfasalazine	S	Oral	Unk, Bid	Pfizer
	Sulfasalazine	S	Subcutaneous	1 Gram, Bid	Pfizer
	Sulfasalazine	S	Unknown	1000 Mg, Unk	Pfizer
	Paracetamol	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported

Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk (Solution Subcutaneous)	Not Reported
Cimzia	S	Unknown	400 Mg, Monthly	Not Reported
Cimzia	S		Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Cyclic Q2wk	Not Reported
Humira	S		Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Q2wk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cortisone	S	Oral	Unk Ointment	Not Reported
Cortisone	S	Unknown	Unk Tablet	Not Reported
Cortisone	S	Oral	25 Mg, Unk Tablet	Not Reported
Cortisone	S		25 Mg, Unk Ointment	Not Reported
Cortisone	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Mg, 1x/Day (1 Every 24 Hours)	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported

Fosamax	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Unknown	Unk (Intra Corpus Cavernosum)	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Unknown	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Hydrocortisone Acetate	S	Oral	Unk	Not Reported
Hydrocortisone Acetate	S	Other	Unk	Not Reported
Hydrocortisone Acetate	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Cetirizine	S	Unknown	Unk	Not Reported
Cetirizine	S	Oral	10 Mg, Unk	Not Reported
Cetirizine	S	Unknown	10 Mg, Unk	Not Reported
Cetirizine	S	Unknown	10 Milligram (5mg/5ml) Unk Syrup	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	25 Milligram	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	10 Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	50 Milligram	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	25 Mg, Unk	Not Reported
Folic Acid	S	Unknown	1 Mg, Unk	Not Reported
Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
Folic Acid	S	Oral	25 Mg, Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	40 Mg, Unk	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Unk	Not Reported

Prednisone	S		1 Mg, Unk	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Golimumab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Golimumab	S	Subcutaneous	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Alendronate Sodium	S	Oral	Unk	Not Reported
Alendronate Sodium	S	Unknown	Unk	Not Reported
Sulfathalidine	S		Unk	Not Reported
Apo Hydroxyquine	S	Unknown	Unk	Not Reported
Cosentyx	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Atasol	C	Unknown	Unk	Not Reported
Ibuprofen	C	Unknown	Unk	Not Reported
Leflunomide	C	Oral	Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	20 Mg, Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Lisinopril	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Prednisolone	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	12701616	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1489		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Leucovorin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	14781801	EXPEDITED (15-DAY)		OT	CA-ROCHE-2107063			Male	CAN

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

Carcinoma; Treatment Failure	Enbrel		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Citalopram Hydrobromide		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	14826053	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-036485			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Drug Intolerance; Impaired Work Ability; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Simponi			S	Unknown	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Remicade			S	Unknown	200 Milligram, Cyclical		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	15345828	EXPEDITED (15-DAY)		OT	CA-ROCHE-2177475		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Contraindicated Product Administered; Fall; Off Label Use; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	00072603	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	15620004	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556866-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Synovitis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	15634991	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105511			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Tooth Loss	Orencia			S	Unknown			Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported
	Zostavax			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Desoximetasone			C	Oral			Not Reported
	Desoximetasone			C	Subcutaneous	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Xeljanz			C	Oral	10 Mg, Bid		Not Reported
	Diclofenac			C	Subcutaneous	100 Mg, Unk		Not Reported
	Cortisone Acetate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	15811039	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2617171-00		58 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	15855371	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-		65 YR	Female	CAN

2015371800

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fall; Fatigue; Femur Fracture; Hepatic Enzyme Increased; Infection; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Off Label Use; Osteoporosis; Pain; Rash; Synovitis	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Week		Pfizer
	Sulfasalazine			S	Unknown	2 G, Unk		Pfizer
	Sulfasalazine			S	Oral	5000 Mg, 1x/Day		Pfizer
	Orencia			S	Unknown	Unk, Monthly		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S		Unk		Not Reported
	Apo-Naproxen			S		Unk		Not Reported
	Naproxen			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, 2x/Day		Not Reported
	Rituxan			S		Unk		Not Reported
	Naproxen Sodium			S		Unk		Not Reported
	Hydroxychloroquine			S		400 Mg, Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Apo-Prednisone			S		Unk		Not Reported
	Methotrexate Sodium			C	Subcutaneous	25 Mg, Weekly		Not Reported
	Naroxin			C		Unk		Not Reported
	Risedronate			C	Oral	35 Mg, Weekly		Not Reported
	Arava			C	Oral	20 Mg, 1x/Day		Not Reported
	Folic Acid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	15887790	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1610		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Nausea; Pain; Product Use Issue; Treatment Failure; Vomiting	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported

Apo-Hydroxyquine	S	Subcutaneous	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Ciclosporin	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Plaquenil S	S	Oral	Not Reported
Plaquenil	S	Oral	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Leflunomide	S	Unknown	Not Reported
Neoral	S	Subcutaneous	Not Reported
Neoral	S	Subcutaneous	Not Reported
Neoral	S	Oral	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Rituximab	S	Intravenous (not	Not Reported

			otherwise specified)	
	Rituximab	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Xeljanz Xr	C	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Actemra	C	Intravenous (not otherwise specified)	Not Reported
	Actemra	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	15933878	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656787-00			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	15936329	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2657755-00		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Drug Ineffective; Infection; Insomnia; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Bp		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Arava			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	16178013	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035747		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Pain;	Diclofenac Sodium			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate Sodium			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Wound	Arava	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous drip		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Unknown		Not Reported

	Sulfasalazine	S	Oral	2 Gram Daily; Therapy Duration- 365	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfathalidine	S	Unknown		Not Reported
	Topicort(Desoximetasone)	S	Subcutaneous		Not Reported
	Xeljanz	S	Unknown	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	16192832	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2741798-00		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abnormal Loss Of Weight; Alopecia; Arthritis; Drug Ineffective; Hepatic Enzyme Abnormal; Myocardial Infarction; Rash	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rosuvastatin			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Clopidogrel Bisulfate			C	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Acetylsalicylic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	16445871	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-056456			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb

	Arava	S	Unknown		Not Reported
	Enbrel	S	Unknown	50 Milligram, Qwk	Not Reported
	Gold	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qd	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Unk, Qd	Not Reported
	Myochrysine	S	Intramuscular	25 Milligram, Qwk	Not Reported
	Rituxan	S	Unknown	1 Gram	Not Reported
	Rituximab	S	Unknown	1000 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	16489797	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2052		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Alopecia; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Nausea; Oedema; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Rituxan			S	Unknown	1/2		Not Reported
	Rituxan			S	Intravenous (not			Not Reported

		otherwise specified)	
Simponi	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Actemra	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Desoximetasone	S	Oral	Not Reported
Folic Acid	S	Unknown	Not Reported
Fosamax	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Cetirizine	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Cortisone Acetate	S	Topical	Not Reported
Naprosyn	C	Unknown	Not Reported
Naprosyn	C	Unknown	Not Reported
Celebrex	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	16801774	EXPEDITED (15-DAY)		OT	PHHY2019CA210752			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	16830502	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2929972-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Hip Arthroplasty; Hypoaesthesia; Joint Swelling; Malaise; Multiple Sclerosis; Musculoskeletal Disorder; Nausea; Vomiting	Humira			S	Subcutaneous	Cyclical		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Lyrica			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported

	Acetaminophen	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	16839479	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019154934			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Lung Disorder; Platelet Count Decreased; Rheumatoid Arthritis; Septic Shock; Synovitis; Unevaluable Event; White Blood Cell Count Decreased	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Tofacitinib			S	Unknown	5 Milligram, Bid		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	16877948	EXPEDITED (15-DAY)		OT	GB-BAUSCH-BL-2019-055587		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthropathy; Lethargy; Myelodysplastic Syndrome; Pancytopenia; Platelet Count Decreased	Metformin			S	Unknown			Santarus
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17272589	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2020013698		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Ibuprofen			S	Oral	Unk (200mg Tablets)		Pfizer
	Hydroxychloroquine			S	Oral	Unk (6 G Missing)		Not Reported

	Naproxen	S	Oral	Unk (750mg Tablets)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17442941	EXPEDITED (15-DAY)		OT	CA-ROCHE-2547878		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Insomnia; Iodine Allergy; Pain; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Venlafaxine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	M-Eslon			C	Unknown			Not Reported
	Morphine			C				Not Reported
	Morphine Sulfate			C				Not Reported
	Statex [Morphine Sulfate]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17442962	EXPEDITED (15-DAY)		HO, OT	GR-IPCA LABORATORIES LIMITED-IPC-2020-GR-000567			Unknown	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Heart Disease Congenital; Respiratory Distress	Hydroxychloroquine			S	Transplacental	Unk		Ipca
	Prednisolone			S	Transplacental	Unk		Not Reported
	Acetylsalicylic Acid			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443256	EXPEDITED (15-DAY)		OT	CA-ROCHE-2549601		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Condition Aggravated; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Thyroid Neoplasm	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443328	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553485		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported

Arava	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Apo-Leflunomide	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443340	EXPEDITED (15-DAY)		OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-237571		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthritis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatic Fibrosis; Insomnia; Pain; Rash; Therapeutic Product Effect Incomplete	Venlafaxine			S	Oral	1 Dosage Form, Daily		Sun
	Enbrel			S	Subcutaneous	1 Dosage Form, Weekly		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	300 Milligram, Daily		Not Reported
	Reactine			C	Unknown	10 Milligram, Daily		Not Reported
	Zopiclone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443383	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553490		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Infliximab	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Adalimumab	S	Unknown	Not Reported
	Actemra	C	Unknown	Not Reported
	Azathioprine	C	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Minocycline	C	Unknown	Not Reported
	Penicillamine	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443467	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553491		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Hepatotoxicity; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443476	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3283788-00		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Cervical Vertebral Fracture; Drug Ineffective; Drug Interaction; Drug Intolerance; Grip Strength Decreased; Hypophagia; Influenza; Joint Range Of Motion Decreased; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Rheumatoid Arthritis; Upper Limb Fracture; Vomiting	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443486	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552643		52 YR	Female	CAN

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

Orencia	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443552	EXPEDITED (15-DAY)		HO	CA-ROCHE-2552666			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443944	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011979			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17444031	EXPEDITED (15-DAY)		OT	CA-ROCHE-2554290		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Osteoarthritis; Synovitis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17444871	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187147		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Joint Swelling; Off Label Use; Pain; Pemphigus; Rash; Rheumatoid Factor Positive; Swelling; Systemic Lupus Erythematosus; Wound	Arava	S	Oral		Not Reported
	Cetirizine	S	Unknown		Not Reported
	Cetirizine	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Desoximetasone	S	Cutaneous		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydrocortisone Acetate	S	Cutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram Daily;	Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Methotrexate	S	Oral	25 Milligram Daily;	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17444898	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187135			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17445348	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552836		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Rheumatoid Arthritis; Sleep Disorder	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17445349	EXPEDITED (15-DAY)		OT	NVSC2020CA025358			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Fatigue; Grip Strength Decreased; Hepatitis; Pain	Methotrexate			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	20 Mg		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Indomethacin			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Imuran			C	Unknown			Not Reported
	Cortisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17445421	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020073533			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pneumonia	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	1 G, Every 12hours		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Every Day		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17445771	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020077926			Female	CAN

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

Blood Disorder; Hepatotoxicity; Pain	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Sulfasalazine	S		500 Mg, Unk	Pfizer
	Arava	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17446119	EXPEDITED (15-DAY)		OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-20-007		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Cardiomegaly; Incorrect Dose Administered; Maculopathy; Nephropathy Toxic; Renal Failure; Retinal Toxicity	Hydroxychloroquine			S	Unknown			Hikma
	Hydroxychloroquine			S	Unknown			Hikma
	Prednisone			C	Unknown			Not Reported
	Mycophenolate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17446901	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1187166			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Pain; Nausea; Neck Pain; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rash; Therapeutic Product Effect Decreased; Weight Decreased	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine		S	Unknown	2000 Gram Daily;	Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17446916	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187154			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Drug Intolerance; Foot Deformity; Inguinal Hernia; Interstitial Lung Disease; Joint Dislocation; Periarticular Disorder; Post-Traumatic Neck Syndrome; Rheumatoid Arthritis	Prednisone			S	Unknown	15 Milligram Daily;		Actavis
	Methotrexate			S	Unknown			Barr
	Calcium Carbonate			S	Oral	3 Dosage Forms Daily;		Not Reported
	Celebrex			S	Unknown	400 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Relafen			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	3000 Milligram Daily;		Not Reported
	Magnesium Aspartate			C	Oral	3 Dosage Forms Daily;		Not Reported
	Omega 3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17446944	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187274			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Diclofenac Sodium			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Folic Acid	S	Unknown	Not Reported
Fosamax	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil[Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17446966	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187287		34 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17446970	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187192			Female	CAN

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

Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Endodontic Procedure; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Pain; Product Dose Omission; Rash; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tooth Infection; Weight Decreased	Prednisone	S	Unknown		Actavis
	Methotrexate	S	Unknown		Barr
	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown	10 Milligram Daily;	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown		Not Reported
	Naproxen	C			Not Reported
	Risedronate Sodium	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17447221	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187169			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypospadias; Low Birth Weight Baby; Maternal Exposure During Pregnancy; Premature Baby	Prednisone			S	Transplacental			Actavis
	Methotrexate			S	Transplacental			Barr
	Hydroxychloroquine			S	Transplacental			Not Reported
	Immune Globulin (Human)			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17447516	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187714			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Sepsis;	Prednisone			S	Oral			Actavis
	Methotrexate			S	Unknown			Barr
	Plaquenil			S	Oral			Not Reported

Therapeutic Response Decreased; White Blood Cell Count Decreased	Arava		S	Oral		Not Reported
	Arava		S	Unknown		Not Reported
	Sertraline Hydrochloride		S	Unknown		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Acyclovir [Aciclovir]		C	Unknown		Not Reported
	Aerius [Ebastine]		C	Oral		Not Reported
	Amitriptyline		C	Oral	25 Milligram Daily;	Not Reported
	Constella		C	Oral	145 Milligram Daily;	Not Reported
	Levofloxacin		C	Unknown		Not Reported
	Lyrica		C	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]		C	Oral		Not Reported
	Sertraline Hydrochloride		C	Unknown		Not Reported
	Vitamin C [Ascorbic Acid]		C	Oral		Not Reported
	Zomig		C	Oral		Not Reported
	Zopiclone		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17447605	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020073610			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Gastric Disorder; Gastric Haemorrhage; Pain; Therapeutic Product Effect Decreased	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Tylenol 8 Hr Arthritis Pain			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17447732	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187228			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; C-Reactive Protein Abnormal; Drug Ineffective; Drug Ineffective; Drug Ineffective; Juvenile Idiopathic Arthritis; Red Blood Cell Sedimentation Rate Abnormal	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2020	17333171	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527581			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2020	17448001	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553779		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Drug Ineffective	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported

	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2020	17448019	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555252			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2020	17448020	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553790		50 YR	Female	CAN

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

Breast Cancer Stage Iii; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2020	17448022	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553470		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Pulmonary Fibrosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2020	17448030	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553811			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Naprosyn [Naproxen]	S	Unknown	Not Reported
	Naprosyn [Naproxen]	S		Not Reported
	Orencia	S	Unknown	Not Reported
	Vioxx	S	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2020	15630530	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105495		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Off Label Use; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Lyrica			C	Oral	Unk		Not Reported
	Lyrica			C	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Enbrel	S	Subcutaneous	1 Df, Qwk		Not Reported
Cimzia	S	Subcutaneous			Not Reported
Arava	C	Unknown			Not Reported
Prednisone	C	Oral			Not Reported
Acetaminophen	C	Unknown			Not Reported
Codeine	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2020	17448256	EXPEDITED (15-DAY)		OT	PHHY2019CA055941		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Enbrel			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk (Single-Use Prefilled Syringe)		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	12310874	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2014345227		49 YR	Female	CAN

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

Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Enbrel	S	Subcutaneous	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	25 Mg, Unk	Pfizer
	Methotrexate	S		25 Mg, Unk	Pfizer
	Sulfasalazine	S	Unknown	1 G, Unk	Pfizer
	Rapamune	S		Unk	Pfizer
	Plaquenil	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	20 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Certolizumab Pegol	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Neoral	S		Unk	Not Reported
	Prograf	S	Unknown	Unk	Not Reported
	Prograf	S	Oral	3.0 Mg, Q12h	Not Reported
	Prograf	S	Oral	2.0 Mg, Q12h	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxyquinoline Sulfate	S	Unknown	Unk	Not Reported
	Tacrolimus	S	Unknown	3 Milligram 1 Every 12 Hours	Not Reported
	Tacrolimus	S	Oral	3 Milligram, 2 Every 1 Day	Not Reported
	Tacrolimus	S	Oral	2 Milligram, 2 Every 1 Day	Not Reported
	Azathioprine	C		25 Mg, Unk	Not Reported
	Imuran	C		25 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	12355072	EXPEDITED (15-DAY)		DS, HO, OT	CA-PFIZER INC-2015306460		41 YR	Female	CAN

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

Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Arthralgia; Arthritis; Arthropathy; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Creatinine Increased; Blood Parathyroid Hormone Decreased; Blood Pressure Systolic Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Decreased Appetite; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Intolerance; Enthesopathy; Erythema; Erythema; Fatigue; Fear Of Injection; General Physical Health Deterioration; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Insomnia; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation	Etanercept	S	Subcutaneous	Unk	Pfizer
	Etanercept	S		Unk	Pfizer
	Etanercept	S		Unk	Pfizer
	Enbrel	S	Subcutaneous	Unk	Pfizer
	Enbrel	S		25 Milligram, 2 Times/Wk	Pfizer
	Enbrel	S		25 Milligram	Pfizer
	Enbrel	S		Unk	Pfizer
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Pfizer
	Enbrel	S	Unknown	20 Milligram, Qd	Pfizer
	Sulfasalazine	S	Unknown	500 Mg, Unk	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Sulfasalazine	S	Oral	1 Gram, Bid	Pfizer
	Infliximab Hospira	S	Intravenous (not otherwise specified)	400 Milligram	Not Reported
	Infliximab Hospira	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
	Ibuprofen	S	Oral	600 Mg, Every 3-4 Hours Regularly	Pfizer
	Ibuprofen	S	Oral	600 Mg, Q4h	Pfizer
	Ibuprofen	S	Oral	600 Milligram	Pfizer
	Methotrexate Sodium	S	Oral	Unk Unk (4.0 Dosage Forms), Qwk	Pfizer
	Methotrexate Sodium	S	Unknown	2.5 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Unknown	15 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Unknown	17.5 Milligram, 4 Times/Wk	Pfizer
	Methotrexate Sodium	S	Unknown	12 Milligram, 4 Times/Wk	Pfizer
	Methotrexate Sodium	S	Unknown	10 Milligram, 4 Times/Wk	Pfizer
	Methotrexate Sodium	S	Unknown	12.5 Milligram, 4 Times/Wk	Pfizer

Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Methotrexate Sodium	S	Unknown	70 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Unknown	2.5 Milligram, Qmo	Pfizer
	Methotrexate Sodium	S	Oral	10 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Oral	7.5 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Oral	10 Milligram, 4 Times/Wk	Pfizer
	Celebrex	S	Oral	200 Milligram, Bid	Pfizer
	Methotrexate Sodium	S	Subcutaneous	12.5 Milligram, Qwk	Unknown
	Methotrexate Sodium	S	Subcutaneous	15 Milligram, 4 Times/Wk	Unknown
	Methotrexate Sodium	S	Subcutaneous	10 Milligram, 4 Times/Wk	Unknown
	Methotrexate Sodium	S	Subcutaneous	17.5 Milligram, 4 Times/Wk	Unknown
	Rituximab	S	Unknown	1000 Milligram, Bid	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Cosentyx	S	Subcutaneous	300 Milligram, Qmo	Not Reported
	Apo Ibuprofen	S	Oral	600 Mg, Unk	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Cyclosporine	S	Oral	Unk	Not Reported
	Apo-Cyclosporine	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Abatacept	S	Unknown	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Golimumab	S	Subcutaneous	Unk (Solution)	Not Reported
	Ustekinumab	S	Subcutaneous	Unk	Not Reported
	Ustekinumab	S	Unknown	Unk	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
	Certolizumab Pegol	S	Unknown	Unk	Not Reported

Leflunomide	S	Oral	Unk	Not Reported
Humira	S	Subcutaneous	40 Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Unknown	Unk	Not Reported
Apremilast	S	Oral	30 Mg, 2x/Day	Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Apremilast	S	Unknown	60 Milligram, Bid	Not Reported
Cyclosporin	S	Oral	Unk	Not Reported
Cyclosporin	S	Unknown	Unk	Not Reported
Otezla	S	Oral	30 Mg, Bid	Not Reported
Otezla	S			Not Reported
Otezla	S			Not Reported
Ciclosporin	S	Oral	Unk	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Sulfamethoxazole	S	Oral	600 Mg, Unk	Not Reported
Motrin	S	Oral	600 Mg, Every 3-4 Hours Regularly	Not Reported
Motrin	S	Oral	600 Mg, Q4h	Not Reported
Motrin	S	Oral	600.0 Mg, Unk	Not Reported
Motrin	S		6 Df, 1x/Day	Not Reported
Motrin	S	Oral	600 Milligram, Qd	Not Reported
Motrin	S	Oral	Unk, Qd	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Alendronate Sodium	S	Unknown	70 Milligram 4 Every One Week	Not Reported

Codeine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Oxyneo	C	Unknown	10 Mg, Unk	Not Reported
Oxyneo	C	Unknown	40 Mg, Unk	Not Reported
Mogadon	C	Unknown	5 Mg, Unk	Not Reported
Uloric	C	Oral	80 Mg, 2x/Day (Freq: 2 Day; Interval: 1)	Not Reported
Uloric	C	Oral	80 Mg, 2x/Day	Not Reported
Uloric	C	Unknown	Unk	Not Reported
Uloric	C		80 Mg, Bid	Not Reported
Uloric	C	Unknown	Unk Mg, Unk	Not Reported
Uloric	C	Oral	8 Milligram, Bid	Not Reported
Colchicine	C	Oral	0.6 Milligram	Not Reported
Colchicine	C	Oral	6 Milligram	Not Reported
Acide Folique	C		Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Nitrazepam	C	Unknown	5 Mg, Unk	Not Reported
Nitrazepam	C	Oral	Unk	Not Reported
Nitrazepam	C		50 Milligram	Not Reported
Oxycodone	C	Unknown	40 Mg, Unk	Not Reported
Oxycodone	C	Unknown	10 Mg, Unk	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported

	Benadryl	C	Unknown	Unk	Not Reported
	Dexilant	C	Unknown	Unk	Not Reported
	Gravol	C	Unknown	Unk	Not Reported
	Febuxostat	C	Unknown	80 Mg, Bid	Not Reported
	Methotrexate Sodium	C	Oral	Unk Unk (4.0 Dosage Forms), Qwk	Not Reported
	Methotrexate Sodium	C		2.5 Milligram 4 Tablets, Once A Week	Not Reported
	Oxycodone Hydrochloride	C	Unknown	10 Mg, Unk	Not Reported
	Oxycodone Hydrochloride	C	Unknown	40 Mg, Unk	Not Reported
	Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Xeljanz	C		Unk	Not Reported
	Naproxen	C		500 Milligram	Not Reported
	Cannabis Sativa	C		Unk	Not Reported
	Actonel	C	Oral	35 Milligram, Qwk	Not Reported
	Vitamin D 3	C	Oral	2000 International Unit	Not Reported
	Risedronate Sodium	C	Oral	35 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	12690990	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1432		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Intramuscular			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported

Product Effect Decreased	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	4-8 Mg/Kg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Oral		Not Reported
	Plaquenil	S	Oral		Not Reported
	Apo-Hydroxyquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Acetylsalicylic Acid	C	Unknown		Not Reported

	Calcium	C	Unknown		Not Reported
	Lantus	C	Subcutaneous		Not Reported
	Lozide	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Naprosyn	C	Unknown	As Necessary	Not Reported
	Prednisone	C	Unknown		Not Reported
	Ramipril	C	Unknown		Not Reported
	Vitamin D	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Asa Arthritis Strength Aspirin	C	Unknown	Strength: 81 Mg	Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Vitamin D3	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	12696569	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1473		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Abnormal Loss Of Weight; Adverse Drug Reaction;	Methotrexate (Trade Name Unknown)			S				Not Reported
Arthropathy; Deafness; Deafness Transitory;	Methotrexate (Trade Name Unknown)			S				Not Reported
Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain;	Methotrexate (Trade Name Unknown)			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported

Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Motrin	S		Not Reported
	Motrin	S		Not Reported
	Motrin	S		Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Arava	S		Not Reported
	Aspirin	S	Unknown	Not Reported
	Aspirin	S		Not Reported
	Aspirin	S		Not Reported
	Aspirin	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Humira	S		Not Reported
	Humira	S		Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Naprosyn	S	Unknown	Not Reported
	Naprosyn	S		Not Reported
	Naprosyn	S		Not Reported
	Naprosyn	S		Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S		Not Reported
	Gold	S		Not Reported
	Gold	S		Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Plaquenil	S		Not Reported
	Plaquenil	S		Not Reported
	Voltaren	S	Unknown	Not Reported
	Voltaren	S		Not Reported
	Voltaren	S		Not Reported
	Voltaren	S		Not Reported
	Acetylsalicylic Acid	S	Unknown	Not Reported
	Acetylsalicylic Acid	S		Not Reported
	Acetylsalicylic Acid	S		Not Reported
	Acetylsalicylic Acid	S		Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported

Apo-Diclofenac	S	Unknown	Not Reported
Diclofenac Potassium	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Oral	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sulfamethoxazole And Trimethoprim	S	Unknown	Not Reported
Vitamin C	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Sulfamethoxazole	S	Unknown	Not Reported
Clopidogrel	S	Unknown	Not Reported
Trimethoprim	S	Unknown	Not Reported
Apo Hydroxychloroquine	S	Unknown	Not Reported
Apo Asa	S	Unknown	Not Reported
Tramadol	S	Unknown	Not Reported
Tramadol Hydrochloride	S	Unknown	Not Reported
Apo-Sulfatrim	S	Unknown	Not Reported
Diclofenac	S	Unknown	Not Reported
Naproxen Sodium	S	Unknown	Not Reported
Ibuprofen	S	Unknown	Not Reported
Diclofenac Sodium	S	Unknown	Not Reported
Naproxen	S	Unknown	Not Reported
Sulfatrim	S	Unknown	Not Reported
Asa	S	Unknown	Not Reported
Gold Sodium Thiomalate	S	Unknown	Not Reported
Acetylsalicylic Acid-Clopidogrel	S	Unknown	Not Reported
Acetylsalicylic Acid-Clopidogrel	S		Not Reported
Acetylsalicylic Acid-Clopidogrel	S		Not Reported
Acetylsalicylic Acid-Clopidogrel	S		Not Reported

	Tramadol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	12701557	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1498		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Breast Cancer; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Infection; Joint Swelling; Loss Of Consciousness; Pain In Extremity; Peripheral Swelling; Product Use Issue; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Gold	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Meloxicam	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	12957589	EXPEDITED (15-DAY)		CA, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-093145			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Arthropathy; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Hip Arthroplasty; Infection; Off Label Use; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram,Every One Day		Not Reported
	Naprosyn [Naproxen]			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	500 Mg, Bid		Not Reported

	Erythromycin	C	Unknown	Not Reported
	Morphine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	13107798	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0119		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Loss Of Personal Independence In Daily Activities; Pain; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Apo Hydroxychloroquin			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Methyl Salicylate			S	Unknown			Not Reported
	Salicylates Nos			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	13929653	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2698		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown	Dose: 730		Not Reported
	Enbrel			S	Unknown	Dose: 731		Not Reported
	Enbrel			S	Unknown	Dose: 4 Year		Not Reported
	Humira			S	Subcutaneous	Dose: 5 Month		Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

Arava	S	Oral	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Cimzia	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Arthrotec	C	Unknown	Not Reported
Imuran	C	Unknown	Not Reported
Vitamin D	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Azathioprine	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	14223525	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021445		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	1 Df, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S				Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5.0 Mg, Bid		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Orencia	S			Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S			Not Reported
Valsartan	C	Unknown	320 Mg, Qd	Not Reported
Xalatan	C	Unknown	50 Mg, Qd	Not Reported
Xalatan	C	Ophthalmic	50 Mg, Qd	Not Reported
Xalatan	C	Unknown	Unk	Not Reported
Xalatan	C	Unknown	50 Mg, Unk	Not Reported
Xalatan	C	Unknown	5.0 Mg, Unk	Not Reported
Dorzolamide + Timolol Genoptim	C	Unknown	Unk, Bid	Not Reported
Estradiol	C	Unknown	6 %, Tid	Not Reported
Furosemide	C	Unknown	40 Mg, Qd	Not Reported
Ergocalciferol	C	Unknown	Unk, Q.Wk.	Not Reported
Estrogel	C	Unknown	0.6 %, Tid	Not Reported
Morphine	C	Unknown	Unk	Not Reported
Morphine	C			Not Reported
Potassium Chloride	C	Unknown	1500 Mg, Qd	Not Reported
Zingiber Officinale	C	Oral	500 Mg, Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Atasol /00020001/	C	Unknown	Unk	Not Reported
Baclofen	C	Unknown	10 Mg, Bid	Not Reported
Calcium	C	Unknown	500 Mg, Unk	Not Reported
Calcium Gluconate	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Levaquin	C	Unknown	500 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	14634541	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1464		54 YR	Male	CAN

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

Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Plaquenil	S	Oral		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine	S	Unknown	Therapy Duration: 730	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Etanercept	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	C	Unknown		Not Reported
	Sodium Aurothiomalate	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported
	Remicade	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	14746351	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009116		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Synovitis; Throat Tightness	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S				Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Supeudol			C	Unknown	Unk		Not Reported
	Supeudol			C	Unknown	5 Mg, Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	14782027	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1172			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	14917342	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-049997			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Burning Sensation; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Unknown	750 Milligram, Q4wk		Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Every 10 Days		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Q4wk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Kevzara			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Rituximab			S	Subcutaneous			Not Reported

	Tofacitinib Citrate	S	Unknown		Not Reported
	Rabeprazole Sodium	C	Oral	20 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	15399919	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083462			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Off Label Use; Pain; Peripheral Swelling; Rash; Skin Ulcer	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	15400531	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083802			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Metals; Arthralgia; Arthropathy; Blood Cholesterol Increased; Gastric Disorder; Granuloma; Off Label Use; Pain In	Orencia			S	Unknown			Bristol Myers Squibb
	Celebrex			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Extremity; Pruritus; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased; Skin Wrinkling; Spinal Osteoarthritis; Therapeutic Product Effect Decreased; Thyroid Disorder	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	15589215	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3173			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Bone Erosion; Contraindicated Product Administered; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Exostosis; Foot Deformity; Headache; Hepatic Cirrhosis; Infection; Joint Dislocation; Joint Stiffness; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Pneumonia; Synovitis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported

Otezla	S	Oral	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous drip	Not Reported
Simponi	S	Subcutaneous	Not Reported
Stelara	S	Subcutaneous	Not Reported
Sirukumab	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Morphine Sulfate	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Dilaudid	C	Unknown	Not Reported
Wellbutrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	15688989	EXPEDITED (15-DAY)		DS, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1053		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alanine Aminotransferase Increased; Alopecia; Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Aspartate Aminotransferase Increased; Asthenia; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Blood Pressure Fluctuation; Body Temperature Decreased; Bone Density Abnormal; C-Reactive Protein Increased; Chills;	Methotrexate (Trade Name Unknown)			S	Oral	Lower Doses Initially And Increased Over The Years Around 1997		Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Contraindicated Product Administered; Cough;	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
Deafness; Decreased Appetite; Disability; Drug	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
Eruption; Drug Ineffective; Drug Intolerance; Drug	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
Tolerance; Drug Tolerance Decreased; Fatigue;	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Gastric Disorder; Granuloma Skin;	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Headache; Hypercalcaemia;	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Hypercholesterolaemia; Hypersensitivity; Infection;	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Inflammation; Insomnia; Limb Deformity; Loss Of	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Personal Independence In Daily Activities; Malaise;	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Mood Swings; Musculoskeletal Pain;	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
Musculoskeletal Stiffness; Nasopharyngitis; Nausea;	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
Neck Mass; Oropharyngeal Pain; Pain;	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
Pain In Extremity; Panniculitis; Peripheral	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
Swelling; Product Use Issue; Product Use Issue;	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
Pyrexia; Rash; Rash Pruritic; Red Blood Cell	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Sedimentation Rate Increased; Rheumatoid	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Arthritis; Rheumatoid Nodule; Rosacea; Skin	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
Necrosis; Skin Ulcer; Somnolence; Stress;	Methotrexate (Trade Name Unknown)	S	Oral	Strength: 2.5 Mg	Not Reported
Swelling; Therapeutic Product Effect Decreased;	Methotrexate (Trade Name Unknown)	S	Unknown	Lower Doses Initially And Incrased Over The Years Around 1997	Not Reported
Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer; Vomiting; Weight	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported

Increased	Methotrexate (Trade Name Unknown)	S	Subcutaneous	25	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	2x/Week	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Indocid	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported

Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Unknown	20	Not Reported
Leflunomide	S	Oral		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Unknown	5 Days Out Of 7	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Indomethacin	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Gold (198 Au) Colloidal	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported

Apo-Prednisone	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Gold	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Codeine	S	Unknown		Not Reported
Alendronate	S	Unknown		Not Reported
Alendronate	S	Unknown		Not Reported
Alendronate	S	Unknown		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Myochrysine	S	Parenteral		Not Reported
Myochrysine	S	Intramuscular	Cyclic	Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Arava	S	Oral		Not Reported
Rituximab	S	Unknown		Not Reported
Alendronic Acid	S	Unknown		Not Reported

Cimzia	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous		Not Reported
Celebrex	S	Unknown		Not Reported
Adalimumab	S	Subcutaneous		Not Reported
Naproxen	S	Unknown		Not Reported
Azathioprine	S	Unknown		Not Reported
Fosamax	S	Unknown		Not Reported
Acetaminophen	S	Oral		Not Reported
Benadryl	S	Oral		Not Reported
Methylprednisolone Sodium Succinate	S	Intravenous (not otherwise specified)		Not Reported
Cymbalta	C	Oral	Nightly	Not Reported
Folic Acid	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported
Xeljanz	C	Oral		Not Reported
Prednisone	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Cyclosporine	C	Unknown		Not Reported
Cyclosporine	C	Unknown		Not Reported
B Complex	C	Unknown		Not Reported
Fish Oil	C	Unknown		Not Reported
Ciprodex	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	15979301	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-014058		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rheumatoid Arthritis;	Abatacept			S	Unknown	Unk		Bristol Myers Squibb

Therapeutic Product Effect Incomplete	Rituxan	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Q6wk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
	Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Unknown	200 Mole, Bid	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q2wk	Not Reported
	Enbrel	S	Unknown	25 Mg, Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Sulfasalazine	C	Unknown	1 Gram, Bid	Not Reported
	Wellbutrin	C	Unknown	Unk, Tablet Extended Release	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	16095151	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2710698-00			Female	CAN

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

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Amoxicillin Trihydrate And Clavulanate Potass	C		Not Reported
	Amoxil	C		Not Reported
	Amoxicillin And Clavulanate Potassium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	16200433	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1110		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Glucose Increased;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Blood Pressure Increased; C-Reactive Protein	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Abnormal; Condition Aggravated;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Contraindicated Product Administered; Drug	Methotrexate (Trade Name Unknown)			S	Subcutaneous	2.5 Mg/Ml		Not Reported
Ineffective; Drug Intolerance; Fatigue;	Methotrexate (Trade Name Unknown)			S	Subcutaneous	4 Every 1 Week		Not Reported
Femur Fracture; Gait Disturbance; Gastric	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
Disorder; Glycosylated Haemoglobin Increased;	Enbrel			S	Unknown			Not Reported
Heart Rate Increased;	Enbrel			S	Unknown			Not Reported
Hepatic Enzyme Increased; Infection; Joint	Enbrel			S	Unknown			Not Reported
Swelling; Loss Of Personal Independence In	Enbrel			S	Unknown			Not Reported
Daily Activities;	Enbrel			S	Unknown			Not Reported

Lymphocyte Count Increased; Malaise; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Nausea; Neutrophil Count Increased; Osteopenia; Pain; Pain In Extremity; Peripheral Swelling; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Somnolence; Synovitis; Tooth Abscess; Treatment Failure; Visual Impairment; Weight Decreased; White Blood Cell Count Increased	Enbrel	S	Unknown	Four Every One Week	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	Four Every One Week	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	4 Every 1 Week	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Unknown		Not Reported

Cimzia	S	Subcutaneous	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Actemra	S	Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Subcutaneous	Not Reported
Tylenol	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Acetaminophen	S	Unknown	Not Reported
Acetaminophen	S	Oral	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Apo-Acetaminophen	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Acetaminophen And Codeine Phosphate	S	Unknown	Not Reported
Apo-Hydro	S	Unknown	Not Reported
Acetaminophen W/Diphenhydramine	S	Unknown	Not Reported

Hydrochloride			
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo Sulfasalazine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Amaryl	S	Unknown	Not Reported
Otezla	S	Unknown	Not Reported
Stelara	S	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Codeine	C	Unknown	Not Reported
Meloxicam	C	Unknown	Not Reported
Tylenol With Codeine No.3	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Celebrex	C	Unknown	Not Reported
Hydromorphone Hcl	C	Unknown	Not Reported
Acetaminophen W/Codeine Phosphate	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Diphenhydramine	C	Unknown	Not Reported
Glyburide	C	Unknown	Not Reported
Hydrochlorothiazide	C	Unknown	Not Reported
Lipitor	C	Unknown	Not Reported
Metformin	C	Unknown	Not Reported
Methylprednisolone	C	Unknown	Not Reported
Percocet	C		Not Reported
Ramipril	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	16507983	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Ill-Defined Disorder; Infection; Limb Discomfort; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Cyclic		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Actonel	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Risedronate	S	Unknown	Not Reported
	Risedronate	S	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	16850467	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019413433			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lung Disorder; Platelet Count Decreased; Rheumatoid Arthritis; Septic Shock; Synovitis; White Blood Cell Count Decreased	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram		Pfizer
	Sulfasalazine			S	Unknown	1 Gram, Bid		Pfizer
	Tofacitinib			S	Unknown	5 Milligram, Bid		Pfizer
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	16854475	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3626		53 YR	Female	CAN

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

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product Administration; Liver Function Test Increased; Rash; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil Sulfate	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Simponi	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17240411	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026873		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid (Therapy Duration: 730)		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Remicade	S	Unknown	Unk		Not Reported
Actemra	S	Unknown	Unk		Not Reported
Bactrim	S	Unknown	Unk		Not Reported
Cimzia	S	Subcutaneous	Unk		Not Reported
Cimzia	S	Unknown	Unk		Not Reported
Enbrel	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Humira	S	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17334290	EXPEDITED (15-DAY)		HO	JP-ADVANZ PHARMA-202001000333			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Sulfamethoxazole/Trimethoprim			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17394928	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0702			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Feeling Abnormal; Rheumatoid Arthritis; Thirst; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17404343	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019507572		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Creatinine Increased; Bone Pain; Decreased Appetite; Drug Ineffective; Dyspnoea; Feeling Hot; Heart Rate Decreased; Loss Of Personal Independence In Daily Activities; Macular Degeneration	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		200 Mg, Daily		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg, Unk		Not Reported
	Shingrix			S		Unk		Not Reported
	Nitro [Glyceryl Trinitrate]			C	Topical	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17411576	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-202001000165			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Transplacental	200 Mg, Qd (Film Coated Tablet)		Concordia
	Predonine			C		Unk		Not Reported
	Tracleer Dt			C		Unk		Not Reported
	Berasus			C		Unk		Not Reported
	Baktar			C		Unk		Not Reported
	Minocycline Hydrochloride			C		Unk		Not Reported
	Alprostadil			C		Unk		Not Reported
	Rebamipide			C		Unk		Not Reported

	Nexium 1-2-3	C	Unk	Not Reported
	Sucralfate	C	Unk	Not Reported
	Ritodrine	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17448570	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0942			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Neutropenia	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported
	Sarilumab			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17448571	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0941		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Neoplasm; Psoriasis; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17448674	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-GSH201905-001299			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium; Retinal Depigmentation; Visual Field Defect	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17448792	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-012554		42 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449079	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2020-00768		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertrophic Cardiomyopathy; Overdose; Thrombocytopenia	Hydroxychloroquine			S	Unknown	300 Milligram, Qd		Lupin
	Metoprolol			C	Unknown	Unk		Not Reported
	Losartan			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449110	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026903			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Crohn'S Disease; Joint Swelling; Nausea; Nephrolithiasis; Pneumonia; Pyelonephritis; Rash; Sinusitis; Urosepsis	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, 1 Every 4 Weeks		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Certolizumab Pegol			C	Unknown	400 Mg, Q.O.Wk.		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk		Not Reported
	Tocilizumab			C	Unknown	8.0 Mg/Kg, (One Evey Four Weeks)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449159	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1188424		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Haematochezia	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown	20 Mg		Barr
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449167	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187785			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil[Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449227	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552826		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported

Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449309	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020073056			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Gastrointestinal Disorder; Hepatitis; Rash	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		50 Mg, 1x/Day		Pfizer
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449310	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020073493			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hepatotoxicity; Nausea; Therapeutic Response Decreased; Transaminases Increased	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Sulfasalazine			S		1000 Mg, 1x/Day		Pfizer
	Hydroxychloroquine Sulfate			S		300 Mg, 1x/Day		Not Reported
	Leflunomide			S	Oral	10 Mg, 1x/Day		Not Reported
	Levothyroxine Sodium			S	Oral	0.075 Ug, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

	Azathioprine	C	50 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449466	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1188414			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Acetaminophen			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Teva
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown	200 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449547	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202002000942			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriasis	Hydroxychloroquine			S		Unk		Concordia
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449615	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1188475		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective;	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Alendronate Sodium			S	Unknown			Actavis

Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Methotrexate	S	Unknown		Barr
	Actemra	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfathalidine	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Golimumab	S	Unknown		Not Reported
	Salazopyrin	C	Unknown		Not Reported

Diclofenac	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17450164	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0964		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Rabeprazole Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17450354	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555260		42 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17450653	EXPEDITED (15-DAY)		HO, OT	US-APPCO PHARMA LLC-2080818		11 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastroenteritis Cryptosporidial; Hypogammaglobulinaemia ; Leukopenia; Neutropenia	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17450830	EXPEDITED (15-DAY)		HO, LT, OT	PT-UNITED THERAPEUTICS-UNT-2020-002924			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Tamponade; Cardiogenic Shock; Serositis	Remodulin Sq			S	Subcutaneous	0.046 Mg/H, Continuing		United Therapeutics
	Prednisolone			S	Unknown	5 Mg		Not Reported
	Mycophenolate Mofetil			S	Unknown	2.5 G		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg		Not Reported

	Bosentan		S	Unknown	250 Mg	Not Reported
	Riociguat		C	Unknown	6 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17450973	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555709		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Tylenol With Codeine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451026	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-012586			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Celebrex	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451038	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020075510			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Empyema; Musculoskeletal Stiffness; Pain	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Oral	Unk, 1x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg/Kg, 1 Every 12 Hours		Pfizer
	Leflunomide			S	Oral	20 Mg, 1x/Day		Not Reported
	Leflunomide			S	Oral	10 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451060	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020075442		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Gait Disturbance; Nerve Compression	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	2 G, Every Day		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Every Day		Not Reported
	Orencia			S	Unknown	125 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451063	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020075503			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Intolerance; Haematochezia; Hepatic Enzyme Increased; Joint Swelling; Muscle Spasms; Nausea; Neuropathy Peripheral; Rash; Skin Burning Sensation	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	1000 Mg, 2x/Day		Pfizer
	Atorvastatin Calcium			S	Oral	40 Mg, 1x/Day		Pfizer
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Plaquenil S			S	Unknown	Unk		Not Reported
	Plaquenil S			S	Oral	400 Mg, 1x/Day		Not Reported
	Acetaminophen			C	Oral	500 Mg, Unk		Not Reported
	Asa Ec			C	Oral	81 Mg, 1x/Day		Not Reported
	Folic Acid			C	Oral	5 Mg, Weekly		Not Reported
	Vitamin D3			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451087	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020075507		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Codeine			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported

Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Unknown	Unk		Not Reported
Adalimumab	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451102	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020075437			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Headache; Hypersensitivity Vasculitis; Hypertension; Musculoskeletal Stiffness; Nausea; Off Label Use; Rash; Respiratory Tract Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Unk		Pfizer
	Xeljanz			S	Oral	50 Mg, 2x/Day		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Mg, Unk		Not Reported
	Atenolol			C	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Colchicine			C	Unknown	Unk		Not Reported
	Coversyl [Perindopril Arginine]			C	Unknown	Unk		Not Reported
	Hctz			C	Unknown	Unk		Not Reported
	Leucovorin [Calcium Folinate]			C	Oral	5 Mg, Weekly		Not Reported
	Levothyroxine Sodium			C	Unknown	Unk		Not Reported
	Methotrexate			C	Intramuscular	12.5 Mg, Weekly		Not Reported

	Ranitidine		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451130	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020077701		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Intolerance; Haematochezia; Joint Swelling; Neuropathy Peripheral; Rash; Skin Burning Sensation	Sulfasalazine			S	Unknown	1000 Mg, 1 Every 12 Hours		Pfizer
	Sulfasalazine			S	Unknown	1000 Mg, 1 Every 12 Hours		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, 1x/Day		Not Reported
	Acetaminophen			C	Oral	500 Mg, Unk		Not Reported
	Asa Ec			C	Oral	81 Mg, 1x/Day		Not Reported
	Atorvastatin			C	Oral	40 Mg, 1x/Day		Not Reported
	Folic Acid			C	Oral	5 Mg, Weekly		Not Reported
	Leflunomide			C	Unknown	20 Mg, Unk		Not Reported
	Vitamin D3			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451149	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020077712			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gout; Pneumonia	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Colchicine			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Januvia			S		Unk		Not Reported

	Metformin	S	Unknown		Not Reported
	Actemra	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451169	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020077721			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Nausea; Neuropathy Peripheral	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Sulfasalazine			S	Oral	1 G, 2x/Day, Every 12 Hours		Pfizer
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Daily		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Depo-Medrol			C	Intra-articular	80 Mg, 1 Every 2 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451236	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-012595			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Intravenous (not otherwise specified)	20 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451321	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552800		53 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451388	NON-EXPEDITED			US-PFIZER INC-2020076679		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Feeling Abnormal; Oedema Peripheral	Xeljanz			S	Oral	5 Mg, 2x/Day (5 Mg One Tablet By Mouth Twice A Day)		Pfizer
	Lyrica			S		Unk, 3x/Day		Pfizer
	Methotrexate Sodium			S		Unk		Unknown
	Prednisone			S		5 Mg, Alternate Day		Not Reported

				(Every Other Day)	
	Prednisone	S		5 Mg, Alternate Day	Not Reported
	Plaquenil	S		Unk	Not Reported
	Hydrochlorothiazide	S		Unk	Not Reported
	Humira	S		Unk	Not Reported
	Methotrexate Sodium	S	Oral	5 Mg, Weekly (2.5 Mg Two Tablet By Mouth One Time A Week)	Not Reported
	Orencia	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17452006	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020075115		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Lampren			S	Oral	100 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	1 Df, 1x/Day		Not Reported
	Noxafil			S	Oral	300 Mg, 1x/Day		Not Reported
	Cholurso			C				Not Reported
	Propranolol			C				Not Reported
	Ethambutol Hydrochloride			C				Not Reported
	Pantoprazole			C				Not Reported
	Tramadol			C				Not Reported
	Aldactone [Spironolactone]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17452106	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1018551		23 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Chest Pain; Respiratory Distress; Tachycardia; Unevaluable Event	Escitalopram			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17452218	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020077853		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Faeces Discoloured; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Liver Function Test Abnormal; Malaise; Meniscus Injury; Neuropathy Peripheral; Off Label Use; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Paraplegia; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Disorder; Spinal Stenosis; Treatment Failure; Upper Respiratory Tract Infection	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	1 Df, Weekly		Pfizer
	Methotrexate Sodium			S				Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Unknown
	Methotrexate Sodium			S				Unknown
	Sulfasalazine			S	Oral	2 G, 1x/Day		Pfizer
	Aclasta			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	20 Mg, 1 Every 1 Day		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, 1 Every 1 Day		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S	Unknown	20 Mg, 1 Every 1 Day		Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported
	Tramacet			S	Oral			Not Reported
	Tramacet			S	Unknown	Unk		Not Reported
	Amitriptyline			C	Unknown			Not Reported

Calcium	C	Unknown		Not Reported
Depo-Medrol	C	Subcutaneous	Unk Unk, Monthly	Not Reported
Depo-Medrol	C	Intramuscular		Not Reported
Ergocalciferol	C	Unknown		Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Lorazepam	C	Unknown	1 Mg, 1 Every 1 Day	Not Reported
Lyrica	C	Oral	150 Mg, 2 Every 1 Day	Not Reported
Metformin	C	Unknown	5 Mg, 1 Every 1 Day	Not Reported
Metformin	C		500 Mg, 2 Every 1 Day	Not Reported
Methylprednisolone Acetate	C	Intramuscular	40 Mg, Monthly	Not Reported
Methylprednisolone Acetate	C	Subcutaneous	40 Mg, Monthly	Not Reported
Methylprednisolone Acetate	C	Subcutaneous	Unk, Monthly	Not Reported
Methylprednisolone Acetate	C	Unknown		Not Reported
Nortriptyline	C	Unknown	2 Df, Unk	Not Reported
Nortriptyline	C			Not Reported
Nortriptyline	C	Unknown		Not Reported
Nortriptyline	C			Not Reported
Nortriptyline Hydrochloride	C	Unknown	20 Mg, 1x/Day	Not Reported
Nortriptyline Hydrochloride	C			Not Reported
Nortriptyline Hydrochloride	C	Unknown		Not Reported
Nortriptyline Hydrochloride	C			Not Reported
Oxycocet	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Premarin	C	Unknown	0.625 Mg, Unk	Not Reported
Risedronate Sodium	C	Unknown	35 Mg, Weekly	Not Reported
Tylenol 8 Hr Arthritis Pain	C	Unknown		Not Reported
Vagifem	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17452244	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020071737		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Blood Pressure Increased; Blood Pressure Systolic Increased; Cataract; Decreased Appetite; Dizziness; Dyspepsia; Heart Rate Decreased; Nausea; Rheumatoid Arthritis; Vomiting; Weight Decreased; Weight Increased	Sulfasalazine			S	Unknown			Pfizer
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Acetaminophen			C	Oral	650 Mg, Unk		Not Reported
	Atorvastatin			C				Not Reported
	Benadryl			C	Oral	50 Mg, Unk		Not Reported
	Cymbalta			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Irbesartan			C				Not Reported
	Lipitor			C	Unknown			Not Reported
	Prednisone			C				Not Reported
	Solu-Medrol			C	Intravenous (not otherwise specified)	100 Mg, Unk		Not Reported
	Tramadol			C	Unknown	Unk Unk, As Needed		Not Reported
	Vitamin D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17452265	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1188323			Male	CAN

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17452272	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187850		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Prednisone			S	Unknown			Actavis
	Acetaminophen			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17452273	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187784			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Tocilizumab	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17452285	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1188453			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Fatigue; Malaise	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Folate			S	Unknown			Not Reported
	Prevacid			C				Not Reported
	Risedronate Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17452569	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2020074362		68 YR	Male	GBR

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

Diffuse Large B-Cell Lymphoma Stage I	Sulfasalazine		S	1 G, 3x/Day (En)	Pfizer
	Hydroxychloroquine		S	200 Mg, 1x/Day	Not Reported
	Diclofenac		C	Unk, As Needed	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17453023	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1188503			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Affective Disorder; Arthralgia; Depression; Drug Ineffective; Frequent Bowel Movements; Gastric Disorder; Glaucoma; Joint Swelling; Musculoskeletal Stiffness; Nausea; Psoriasis	Prednisone			S	Unknown	25 Milligram Daily;		Actavis
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17453996	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1188808		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Eliquis Film Coated			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	5 Milligram Daily;		Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17453997	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1188754			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Bowel Movement Irregularity; Depression; Gastric Disorder; Glaucoma; Nausea; Psoriasis; Treatment Failure	Prednisone			S	Unknown	25 Milligram Daily;		Actavis
	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	2.1429 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Varicella Zoster Vaccine Live			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17454177	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-013596			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram, Qd	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	1 Gram, Bid	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	9426564	EXPEDITED (15-DAY)		HO, OT	US-SANOFI-AVENTIS-2013SA075840		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alopecia; Balance Disorder; Cervical Radiculopathy; Condition Aggravated; Contusion; Cutaneous Lupus Erythematosus; Dehydration; Depressed Mood; Depression; Diarrhoea; Fatigue; Gastritis; Gastroenteritis Viral; Grip Strength Decreased; Headache; Hot Flush; Limb Discomfort; Multiple Sclerosis Relapse; Nausea; Rash; Spinal Pain; Toothache; Vision Blurred; Visual Impairment	Teriflunomide			S	Oral	7 Mg,Qd		Sanofi
	Teriflunomide			S	Oral	14 Mg,Qd		Sanofi
	Plaquenil			S				Sanofi
	Cymbalta			C	Unknown	90 Mg,1x		Not Reported
	Cymbalta			C				Not Reported
	Ritalin			C	Unknown	5 Mg,1x		Not Reported
	Orsythia			C		28 U, 1x		Not Reported
	Omeprazole			C	Unknown	20 Mg,1x		Not Reported
	Vitamin D3			C	Unknown	1000 Iu,1x		Not Reported
	Cyanocobalamin			C	Unknown	2000 Ug,1x		Not Reported
	Trazodone			C	Unknown	100 Mg,1x		Not Reported
	Trazodone			C				Not Reported
	Zanaflex			C	Unknown	4 Mg,1x		Not Reported

	Carbamazepine		C	Unknown	300 Mg,Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	11115474	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-15K-028-1389528-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Drug Ineffective; Foot Operation; Loss Of Consciousness; Mobility Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	11618838	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-15K-028-1476816-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Ineffective; Ill-Defined Disorder; Loss Of	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported

Consciousness; Loss Of Consciousness; Mobility Decreased; Mobility Decreased; Musculoskeletal Disorder	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	12253776	EXPEDITED (15-DAY)		DS	CA-ABBVIE-16K-028-1600446-00			Female	CAN

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

Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	13118364	EXPEDITED (15-DAY)		DS, HO, OT	CA-CELLTRION INC.-2015CA012467			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	400 Milligram		Not Reported
Abnormal; Alanine Aminotransferase Increased; Arthralgia;	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
Arthritis; Arthropathy;	Etanercept			S	Subcutaneous	Unk		Not Reported
Aspartate Aminotransferase Increased; Basal Cell	Etanercept			S	Unknown	Unk		Not Reported
Carcinoma; Blood Creatinine Increased;	Etanercept			S	Unknown	Unk		Not Reported
Blood Parathyroid Hormone Decreased;	Enbrel			S	Subcutaneous	Unk		Not Reported
Blood Pressure Systolic Increased; C-Reactive	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Not Reported
Protein Abnormal;	Enbrel			S		25 Milligram		Not Reported
Contraindicated Product Administered; Decreased	Enbrel			S		Unk		Not Reported
Appetite; Diarrhoea; Drug	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
Eruption; Drug Hypersensitivity; Drug	Enbrel			S	Unknown	20 Milligram, Qd		Not Reported
Intolerance; Enthesopathy;	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
Erythema; Erythema;	Sulfasalazine			S	Unknown	Unk		Not Reported
Fatigue; Fear Of Injection;	Sulfasalazine			S	Oral	1 Gram, Bid		Not Reported
General Physical Health Deterioration; Granuloma	Ibuprofen			S	Oral	600 Mg, Every 3-4 Hours Regularly		Not Reported
Skin; Headache;	Ibuprofen			S	Oral	600 Mg, Q4h		Not Reported
Hypercalcaemia; Inflammation; Infusion	Ibuprofen			S	Oral	600 Milligram		Not Reported
Related Reaction;	Methotrexate Sodium			S	Oral	Unk Unk (4.0 Dosage Forms), Qwk		Not Reported
Insomnia; Joint Injury;	Methotrexate Sodium			S	Unknown	2.5 Milligram, Qwk		Not Reported
Joint Swelling; Loss Of Personal Independence In	Methotrexate Sodium			S	Unknown	10 Milligram, Qwk		Not Reported
Daily Activities;	Methotrexate Sodium			S	Unknown	15 Milligram, Qwk		Not Reported

Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Methotrexate Sodium	S	Unknown	17.5 Milligram, 4 Times/Wk	Not Reported
	Methotrexate Sodium	S	Unknown	12 Milligram, 4 Times/Wk	Not Reported
	Methotrexate Sodium	S	Unknown	10 Milligram, 4 Times/Wk	Not Reported
	Methotrexate Sodium	S	Unknown	12.5 Milligram, 4 Times/Wk	Not Reported
	Methotrexate Sodium	S	Unknown	70 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Unknown	2.5 Milligram, Qmo	Not Reported
	Methotrexate Sodium	S	Oral	10 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Oral	7.5 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Oral	10 Milligram, 4 Times/Wk	Not Reported
	Celebrex	S	Oral	200 Milligram, Bid	Not Reported
	Methotrexate Sodium	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Milligram, 4 Times/Wk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Milligram, 4 Times/Wk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	17.5 Milligram, 4 Times/Wk	Not Reported
	Rituximab	S	Unknown	1000 Milligram, Bid	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Cosentyx	S	Subcutaneous	300 Milligram, Qmo	Not Reported
	Apo Ibuprofen	S	Oral	600 Mg, Unk	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Cyclosporine	S	Oral	Unk	Not Reported
	Apo-Cyclosporine	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Abatacept	S	Unknown	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported

Golimumab	S	Subcutaneous	Unk (Solution)	Not Reported
Ustekinumab	S	Subcutaneous	Unk	Not Reported
Ustekinumab	S	Unknown	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Certolizumab Pegol	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Humira	S	Subcutaneous	40 Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Unknown	Unk	Not Reported
Apremilast	S	Oral	30 Mg, 2x/Day	Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Apremilast	S	Unknown	60 Mg, Bid	Not Reported
Cyclosporin	S	Oral	Unk	Not Reported
Cyclosporin	S	Unknown	Unk	Not Reported
Otezla	S	Oral	30 Mg, Bid	Not Reported
Otezla	S		Unk	Not Reported
Otezla	S		Unk	Not Reported
Ciclosporin	S	Oral	Unk	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Sulfamethoxazole	S	Oral	600 Mg, Unk	Not Reported
Motrin	S	Oral	600 Mg, Every 3-4 Hours Regularly	Not Reported
Motrin	S	Oral	600 Mg, Q4h	Not Reported
Motrin	S	Oral	600.0 Mg, Unk	Not Reported
Motrin	S		6 Df, 1x/Day	Not Reported
Motrin	S	Oral	600 Milligram, Qd	Not Reported
Motrin	S	Oral	Unk, Qd	Not Reported

Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Alendronate Sodium	S	Unknown	70 Milligram 4 Every One Week	Not Reported
Codeine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Oxyneo	C	Unknown	10 Mg, Unk	Not Reported
Oxyneo	C	Unknown	40 Mg, Unk	Not Reported
Mogadon	C	Unknown	5 Mg, Unk	Not Reported
Uloric	C	Oral	80 Mg, 2x/Day (Freq: 2 Day; Interval: 1)	Not Reported
Uloric	C	Oral	80 Mg, 2x/Day	Not Reported
Uloric	C	Unknown	Unk	Not Reported
Uloric	C		80 Mg, Bid	Not Reported
Uloric	C	Unknown	Unk Mg, Unk	Not Reported
Uloric	C	Oral	8 Milligram, Bid	Not Reported
Colchicine	C	Oral	0.6 Milligram	Not Reported
Colchicine	C	Oral	6 Milligram	Not Reported
Acide Folique	C		Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported

	Nitrazepam	C	Unknown	5 Mg, Unk	Not Reported
	Nitrazepam	C	Oral	Unk	Not Reported
	Nitrazepam	C		50 Milligram	Not Reported
	Oxycodone	C	Unknown	40 Mg, Unk	Not Reported
	Oxycodone	C	Unknown	10 Mg, Unk	Not Reported
	Oxycodone	C	Unknown	Unk	Not Reported
	Benadryl	C	Unknown	Unk	Not Reported
	Dexilant	C	Unknown	Unk	Not Reported
	Gravol	C	Unknown	Unk	Not Reported
	Febuxostat	C	Unknown	80 Mg, Bid	Not Reported
	Methotrexate Sodium	C	Oral	Unk, 1/Week	Not Reported
	Methotrexate Sodium	C		2.5 Milligram 4 Tablets, Once A Week	Not Reported
	Oxycodone Hydrochloride	C	Unknown	10 Mg, Unk	Not Reported
	Oxycodone Hydrochloride	C	Unknown	40 Mg, Unk	Not Reported
	Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Xeljanz	C		Unk	Not Reported
	Naproxen	C		500 Milligram	Not Reported
	Cannabis Sativa	C		Unk	Not Reported
	Actonel	C	Oral	35 Milligram, Qwk	Not Reported
	Vitamin D 3	C	Oral	2000 International Unit	Not Reported
	Risedronate Sodium	S	Oral	35 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	13516208	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-037950		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Condition	Orencia			S	Unknown			Bristol Myers Squibb

Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Neutropenia; Off Label Use; Platelet Count Decreased; Respiratory Tract Infection Viral; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Actemra		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Hydroxychloroquine Phosphate		S	Unknown	200 Mg, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	200 Milligram, Qd	Not Reported
	Xeljanz		S	Oral	5 Mg, Bid	Not Reported
	Hydroxychloroquine		S	Unknown	200 Mg, Qd	Not Reported
	Apo-Leflunomide		S	Unknown	20 Mg, Qd	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	200 Milligram, Qd	Not Reported
	Etanercept		S	Unknown		Not Reported
	Ibuprofen		C	Unknown		Not Reported
	Folic Acid		C	Unknown		Not Reported
	Ketorolac		C	Unknown		Not Reported
	Methotrexate		C	Unknown	20 Mg, Qwk	Not Reported
	Naproxen		C	Unknown		Not Reported
	Prednisone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	13525808	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1965986-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	13537999	EXPEDITED (15-DAY)		HO, LT	CA-ABBVIE-17K-028-1972796-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	14138176	EXPEDITED (15-DAY)		OT	CA-SA-2014SA144669		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Incorrect Route Of Product Administration; Infection; Pneumonia; Synovitis	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Methotrexate			S	Intra-articular	Unk Unk,Unk		Not Reported
	Methotrexate			S	Intra-arterial	Unk Unk,Unk		Not Reported
	Naproxen Sodium			S	Unknown	Unk Unk,Unk		Not Reported
	Celecoxib			S	Unknown	Unk Unk,Unk		Not Reported
	Prednisone			S	Unknown	5 Mg,Unk		Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Enbrel			S	Subcutaneous	Unk Unk,Qw		Not Reported
	Gold			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg,Qw		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	14235931	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3893		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported

Methotrexate (Trade Name Unknown)	S	Subcutaneous	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Azathioprine	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Humira	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Minocycline	S	Unknown	Not Reported
Minocycline	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported

Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Oral		Not Reported
Apo-Azathioprine	S	Unknown		Not Reported
Apo-Azathioprine	S	Unknown		Not Reported
Minocycline Hydrochloride	S	Unknown		Not Reported
Minocycline Hydrochloride	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Apo-Minocycline	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400	Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Leflunomide	C	Unknown	20 Unk	Not Reported
Leflunomide	C	Unknown		Not Reported
Hydroxychloroquine	C	Unknown		Not Reported
Hydroxychloroquine	C	Subcutaneous		Not Reported
Hydroxychloroquine	C	Unknown		Not Reported
Amoxil	C	Unknown		Not Reported
Bcg Vaccine	C	Unknown		Not Reported
Gold	C	Unknown		Not Reported
Clavulin	C	Unknown		Not Reported
Clavulin	C	Unknown		Not Reported
Amoxicillin Trihydrate And Clavulante Potass	C	Unknown		Not Reported
Adalimumab	C	Unknown		Not Reported
Risedronate	C	Unknown		Not Reported
Amoxicillin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	14408887	EXPEDITED (15-DAY)		HO, LT	CA-ABBVIE-18K-028-2225316-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ilaris			S	Subcutaneous	Single-Use Vial Powder For Solution		Not Reported
	Ilaris			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Remicade			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported

	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	14532984	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-ABBVIE-18K-028-2254850-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15395225	NON-EXPEDITED			US-PFIZER INC-2018371106		44 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15712130	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2588065-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Mefenamic Acid	C		Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C		Not Reported
	Tylenol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15715888	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2588290-00		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15716038	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587979-00			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15880483	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2019002469			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		162 Milligram		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Solution	Not Reported
	Imuran	C	Subcutaneous	50 Mg, Once Daily (Qd)	Not Reported
	Azathioprine	C	Subcutaneous	50 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Remicade	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Simponi	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15939703	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2658273-00		50 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15939769	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2658337-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C	Unknown	Extended Release Tablet		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15941600	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2658637-00		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Limb	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Operation; Peripheral Swelling; Rash; Tenosynovitis; Urticaria; Wrist Surgery	Codeine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rocuronium Bromide	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Rocuronium	S	Unknown	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15941848	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2659005-00		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Lyrica	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15993853	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2672993-00		59 YR	Female	CAN

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

	Desipramine	C			Not Reported
	Rosuvastatin Calcium	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	16174468	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2736324-00			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	16284690	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019017151		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Use In Unapproved Indication; Psoriatic Arthropathy; Rheumatoid Arthritis; Uveitis	Cimzia			S	Subcutaneous			Ucb
	Cosentyx			S		Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Otezla			S		Unk		Not Reported
	Remicade			S	Intravenous drip	Unk		Not Reported

	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Sulfasalazine	S		Unk, Once Daily (Qd)	Not Reported
	Sulfasalazine	S		2 Gram	Not Reported
	Enbrel	S		Unk	Not Reported
	Hydroxychloroquine Sulfate	S		400 Milligram	Not Reported
	Methotrexate	C	Subcutaneous	20 Milligram	Not Reported
	Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	16460073	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2822502-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Hydro			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	16861198	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3753			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Lung Disorder; Platelet Count	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Decreased; Rheumatoid Arthritis; Septic Shock; Synovitis; Unevaluable Event; White Blood Cell Count Decreased	Sulfasalazine		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Tofacitinib		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17069514	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-201911001949			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Methotrexate			S	Subcutaneous	25 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17370881	EXPEDITED (15-DAY)		DE, HO, OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-20-004		77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Drug Ineffective; Pancytopenia	Imunoglobulin (Immunoglobulin G Human)			S	Unknown			Not Reported
	Immunoglobulin (Iggiv)			S	Intravenous (not otherwise specified)			Not Reported
	Imunoglobulin (Immunoglobulin G Human)			S				Not Reported
	Dexamethasone			S	Oral			Westward
	Dexamethasone			S				Westward
	Dexamethasone			S				Westward
	Hydroxychloroquine			S	Unknown			Westward
	Bortezomib			S	Intravenous (not otherwise specified)			Not Reported
	Bortezomib			S	Subcutaneous			Not Reported

Bortezomib	S	Intravenous (not otherwise specified)	Not Reported
Bortezomib	S	Intravenous (not otherwise specified)	Not Reported
Bortezomib	S	Intravenous (not otherwise specified)	Not Reported
Bortezomib	S	Intravenous (not otherwise specified)	Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	Not Reported
Thalidomide	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Iron	C	Intravenous (not otherwise specified)	Not Reported
Tadalafil	C	Unknown	Not Reported
Ambrisentan	C	Unknown	Not Reported
Ambrisentan	C	Unknown	Not Reported
Lasix	C	Unknown	Not Reported
Rituximab	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17416957	EXPEDITED (15-DAY)		DS, OT	US-ADVANZ PHARMA-202002000701			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; End Stage Renal Disease;	Hydroxychloroquine			S	Unknown	300 Mg, Qd ((6.5 Mg/Kg		Concordia

Maculopathy; Overdose; Retinopathy				Actual Body Weightper Day)		
	Hydroxychloroquine	S	Unknown	400 Mg, Qd (200 Mg Twice Daily,8.2 Mg/Kg Actual Body Weight Per Day)		Concordia
	Hydroxychloroquine	S		400 Mg, Qd (8 Mg/Kg Actual Body Weightunk		Concordia
	Prednisone	C		Unk		Not Reported
	Mycophenolate Mofetil	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17454316	EXPEDITED (15-DAY)		OT	CA-ROCHE-2556590		74 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17454391	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555707			Female	CAN

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

Arthritis	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17454474	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-013659			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	25 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17454489	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-			Female	CAN

BMS-2020-013781

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	200 Milligram, Bid		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17454580	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-000601			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Condition Aggravated; Oedema Peripheral	Hydroxychloroquine			S	Unknown	200 Milligram		Ipca
	Paracetamol			C	Unknown	Take One Or Two Tablets Up To Four Times A Day ...		Not Reported
	Trimbow			C	Respiratory	4 Dosage Form, Qd		Not Reported

			(inhalation)		
	Clenil Modulite	C	Respiratory (inhalation)	4 Dosage Form, Qd	Not Reported
	Terbutaline	C	Respiratory (inhalation)	1 Dosage Form, Prn	Not Reported
	Atorvastatin	C	Unknown	1 Dosage Form, Qd	Not Reported
	Levothyroxine	C	Unknown	1 Dosage Form, Qd	Not Reported
	Prednisolone	C	Unknown	1 Dosage Form, Qd	Not Reported
	Lansoprazole	C	Unknown	1 Dosage Form, Qd	Not Reported
	Alendronic Acid	C	Unknown	1 Dosage Form, Q.W	Not Reported
	Cetirizine	C	Unknown	1 Dosage Form, Qd	Not Reported
	Simvador	C	Unknown	1 Dosage Form, Hs	Not Reported
	Furosemide	C	Unknown	2 Dosage Form, Qd	Not Reported
	Braltus	C	Respiratory (inhalation)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17454626	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0977			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Disorder; Hepatotoxicity; Pain	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17454794	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-014130			Female	CAN

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

Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Orencia	S	Unknown			Bristol Myers Squibb
	Actemra	S	Unknown			Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate	S	Unknown	20 Milligram		Not Reported
	Sulfasalazine	S	Unknown	1 Gram, Bid		Not Reported
	Xeljanz	C	Oral	50 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17454967	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187769			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17455012	NON-EXPEDITED		HO, OT	AU-AMGEN-AUSSP2020029522			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Ageusia; Arthralgia; Depression; Dna Antibody Negative; Drug Interaction; Fibromyalgia; Gait Disturbance; Liver Function Test Abnormal; Migraine; Nausea; Panic Attack; Paraesthesia; Psoriasis; Psoriatic Arthropathy; Respiratory Syncytial Virus Infection; Sleep Disorder; Suicidal Ideation; Systemic Lupus Erythematosus; Tachyarrhythmia; Type 1 Diabetes Mellitus; Urinary Tract Infection; Viral Tonsillitis	Ivabradine			S	Unknown	7.5 Milligram, Bid		Amgen
	5-Methyltetrahydrofolate			S	Unknown	Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			S	Unknown	100 Milligram		Not Reported
	Cannabis Sativa Oil			S	Unknown	Unk		Not Reported
	Colecalciferol			S	Unknown	Unk		Not Reported
	Endone			S	Oral	5 Milligram, Qd		Not Reported
	Glucagen [Glucagon Hydrochloride]			S	Unknown	Unk		Not Reported
	Glyceryl Trinitrate			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram 2x A Week		Not Reported
	Mirena			S	Unknown	52 Milligram		Not Reported
	Novorapid			S	Subcutaneous	Unk		Not Reported
	Oxycontin			S	Oral	10 Milligram, Bid		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Prasugrel			S	Unknown	10 Milligram, Qd		Not Reported
	Sildenafil			S	Oral	12.5 Milligram		Not Reported
	Mycophenolate Mofetil			S	Oral	1500 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram, 2x A Week		Not Reported
	Methotrexate			S	Unknown	10 Milligram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Rosuvastatin			S	Unknown	10 Milligram		Not Reported
	Ezetimibe			S	Unknown	10 Milligram		Not Reported

Ramipril	S	Unknown	Unk		Not Reported
Topiramate	S	Unknown	200 Milligram		Not Reported
Leflunomide	S	Unknown	Unk		Not Reported
Reboxetine	S	Unknown	8 Milligram, Qd		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Prednisolone	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Cyanocobalamin	S	Unknown	Unk		Not Reported
Folic Acid	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17455030	EXPEDITED (15-DAY)		OT	GB-EMCURE PHARMACEUTICALS LTD-2015-EPL-0087		69 YR	Female	GBR

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17455416	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1188810			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Joint Arthroplasty; Rheumatoid Arthritis; Weight Increased; Wheelchair User	Prednisone			S	Unknown	6.25 Milligram Daily;		Actavis
	Methotrexate			S	Unknown			Barr
	Acetaminophen			S	Unknown			Not Reported
	Indometacin			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported

	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Statex (Morphine Sulfate)	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17455636	EXPEDITED (15-DAY)		OT	CA-SA-2020SA044419			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Haemorrhoids; Rectal Haemorrhage	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Methotrexate			C		Unk		Not Reported
	Tofacitinib			C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17455822	EXPEDITED (15-DAY)		OT	CA-ROCHE-2556596			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17455825	EXPEDITED (15-DAY)		OT	CA-ROCHE-2556141		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17455835	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-084092		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Tramadol Hydrochloride			S	Unknown	Unk		Aurobindo
	Sulfamethoxazole;Trimethoprim			S	Unknown	Unk		Not Reported
	Apo-Diclofenac			S	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Diclofenac Potassium			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Intracardiac	Unk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Plaquenil			S	Intracardiac	Unk		Not Reported
	Mortin			S	Intracardiac	Unk		Not Reported
	Voltaren			S	Intracardiac	Unk		Not Reported
	Acetylsalicylic Acid;Clopidogrel			S	Intracardiac	Unk		Not Reported
	Sodium Aurothiomalate			S	Intracardiac	Unk		Not Reported
	Diclofenac			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17455855	EXPEDITED (15-DAY)		OT	CA-ROCHE-2556483			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17455961	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020006941			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Lupus-Like Syndrome; Swelling Face	Cimzia			S	Subcutaneous	Unk		Ucb
	Arava			S				Not Reported
	Methotrexate			S				Not Reported
	Mycophenolate Sodium			S		Unk, 2x/Day (Bid)		Not Reported
	Plaquenil Sulfate			S				Not Reported
	Prednisone			S				Not Reported
	Remicade			S				Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17456198	EXPEDITED (15-DAY)		HO, OT	GB-ADVANZ PHARMA-202002000973			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Infective	Prednisolone			S		Unk		Concordia

Tenosynovitis; Vasculitic Ulcer	Prednisolone		S	Reduse	Concordia
	Hydroxychloroquine		S	Unk	Not Reported
	Hydroxychloroquine		S	Increased Dose	Not Reported
	Hydroxychloroquine		S	Reduse	Not Reported
	Azathioprine		S	Unk	Not Reported
	Azathioprine		S	Reduse	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17456353	EXPEDITED (15-DAY)		OT	NVSC2020IN045134		41 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Abscess; Condition Aggravated; Depressed Level Of Consciousness; Nocardiosis	Methotrexate			S	Unknown	10 Mg, Qw		Not Reported
	Prednisolone			S	Unknown	30 Mg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	200 Unk, Qd		Not Reported
	Sulfamethoxazole And Trimethoprim			C	Intravenous (not otherwise specified)	15 Mg/Kg Divided In Three Doses		Not Reported
	Amikacin			C	Intravenous (not otherwise specified)	7.5 Mg/Kg, Bid		Not Reported
	Meropenem			C	Intravenous (not otherwise specified)	500 Mg Every 6 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17456398	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019546029		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Fatigue; Lower Respiratory Tract Infection; Off Label Use	Sulfasalazine			S	Unknown	Unk		Pfizer
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17456606	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1189404		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Arthralgia; Blister; Chills; Erythema; Lethargy; Neutrophil Count Increased; Oedema; Pain; Pain Of Skin; Palmar Erythema; Pyrexia; Rash Pruritic; Rash Pustular; Rebound Effect; Skin Exfoliation; Swelling; White Blood Cell Count Increased	Methylprednisolone Sodium Succinate			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17456924	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1019498		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Varicella Zoster Virus Infection	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Prednisone			S	Unknown	40 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	Tapered Down From 40 Mg/Day To 20 Mg/Day Over The Previous 4 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17458210	EXPEDITED (15-DAY)		DS	CA-ABBVIE-20K-028-3290536-00			Female	CAN

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

Arthropathy; Dizziness; Gastrointestinal Disorder; Headache; Hypotension; Joint Noise; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Psoriatic Arthropathy; Rheumatoid Arthritis; Sensitivity To Weather Change; Therapeutic Product Effect Decreased; Vaginal Haemorrhage; Vomiting; Weight Increased	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Leucovorin	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Arava	C		Not Reported
	Calcium Citrate	C		Not Reported
	Magnesium Citrate Forte	C		Not Reported
	Citalopram Hydrobromide	C		Not Reported
	Clobetasol Propionate	C	Topical	Not Reported
	Escitalopram Oxalate	C		Not Reported
	Naproxen	C		Not Reported
	Pantoprazole Magnesium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17458220	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020006969		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Rheumatoid Arthritis; Sleep Disorder	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S				Not Reported
	Methotrexate			C				Not Reported
	Orencia			C				Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Otezla			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S				Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Salazopyrin			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sirukumab			S				Not Reported

	Sulfasalazine	S				Not Reported
	Ustekinumab	S				Not Reported
	Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17458254	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1190225		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Cardiac Failure; Cardiotoxicity; Hypertrophic Cardiomyopathy; Overdose	Hydroxychloroquine			S	Unknown	300 Milligram Daily;		Teva
	Metoprolol			C	Unknown			Not Reported
	Losartan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17458528	EXPEDITED (15-DAY)		OT	CA-SA-2020SA045267			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Diarrhoea; Retinal Toxicity	Leflunomide			S		200 Mg, Qod		Sanofi
	Hydroxychloroquine			S		400 Mg, Qd		Sanofi
	Methotrexate			C	Oral	20 Mg		Not Reported
	Methotrexate			C	Intramuscular	20 Mg		Not Reported
	Sulfasalazine			C		1 G, Bid		Not Reported
	Prednisone			C		Unk		Not Reported
	Asa Ec			C		650 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17458535	EXPEDITED (15-DAY)		OT	CA-SA-2020SA045718			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Meningitis; Treatment Failure;	Hydroxychloroquine			S	Oral	200 Mg, Qd (1 And 1/2 Tablets)		Sanofi

Unevaluable Event	Leflunomide	S		20 Mg, Qd	Sanofi
	Leflunomide	S		20 Mg, Qd	Sanofi
	Prednisone	S		(On And Off , Last Taken In Jun -2019)	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Actemra	S			Not Reported
	Remicade	S			Not Reported
	Methotrexate	C		20 Mg, Qw	Not Reported
	Sulfasalazine	C		Unk	Not Reported
	Enbrel	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	9643129	EXPEDITED (15-DAY)		OT	CA-ROCHE-1287733		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Pressure Fluctuation; Drug Hypersensitivity; Eye Disorder; Fatigue; Fibromyalgia; Infusion Related Reaction; Menopause; Oxygen Saturation Decreased; Pain; Rheumatoid Arthritis; Thermal Burn	Rituxan			S	Intravenous (not otherwise specified)	Most Recent Dose Prior To Sae: 06/May/2010, 17/Jun/2014, 26/Apr/2016		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Effexor			S	Unknown	Dosage Not Specified		Not Reported
	Acetaminophen			C	Oral			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Arthrotec			C				Not Reported
	Methotrexate			C				Not Reported
	Folic Acid			C				Not Reported
	Nortriptyline			C	Unknown	As Required		Not Reported
	Diphenhydramine Hcl			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Doxycyclin [Doxycycline]			C				Not Reported
	Restasis			C				Not Reported

Citalopram Hydrobromide	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	12913694	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-053149		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Arthropathy; Bone Erosion; Condition Aggravated; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Liver Function Test Increased; Off Label Use; Peripheral Swelling; Platelet Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Crestor			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Rosuvastatin Calcium			S	Oral	0.5 Milligram, Bid		Not Reported
	Rosuvastatin Calcium			S	Oral	5.0 Milligram, Bid		Not Reported
	Imuran [Azathioprine]			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported

	Cimzia	S	Subcutaneous	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Rosuvastatin	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown		Not Reported
	Rosuvastatin	S	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Cephalexin [Cefalexin]	C	Unknown	500 Milligram, Qid	Not Reported
	Coversyl [Perindopril Erbumine]	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	10 Milligram, Qd	Not Reported
	Allopurinol	C	Unknown	200 Milligram, Qd	Not Reported
	Cephalexin Monohydrate	C	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	13015479	EXPEDITED (15-DAY)		OT	CA-ROCHE-1865701		56 YR	Female	CAN

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

	Statex [Morphine Sulfate]	C	Unknown		Not Reported
	Folic Acid	C			Not Reported
	Hydrodiuril	C	Unknown		Not Reported
	Orencia	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	15002514	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2018M1039822		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Maculopathy; Retinopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Methotrexate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	15059046	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015918		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pneumonia	Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Unk, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Salazopyrin			S	Unknown	Unk		Not Reported
	Actemra			C	Unknown	Unk		Not Reported
	Align			C	Unknown	Unk		Not Reported
	Loperamide			C	Oral	2 Mg, Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

Pantoprazole	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported
Celebrex	C	Unknown	Unk		Not Reported
Bifidobacterium Bifidum	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	15067535	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015876		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Hepatic Enzyme Abnormal; Pneumonia; Rheumatoid Arthritis; Vomiting	Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Salazopyrin			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Loperamide			C	Oral	2 Mg, Unk		Not Reported
	Pantoprazole			C	Unknown	Unk, Tid		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Actemra			C	Unknown	Unk		Not Reported
	Align			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	15665414	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2570644-00		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S				Not Reported

Abdominal Pain Upper;	Humira 40mg/0.8ml	S		Not Reported
Abdominal Pain Upper;	Humira 40mg/0.8ml	S		Not Reported
Abdominal Pain Upper;	Arava	S	Oral	Not Reported
Abnormal Loss Of Weight;	Arava	S		Not Reported
Abnormal Loss Of Weight;	Arava	S		Not Reported
Adverse Drug Reaction;	Arava	S		Not Reported
Adverse Reaction;	Diclofenac Potassium	S	Unknown	Not Reported
Arthropathy; Arthropathy;	Enbrel	S	Subcutaneous	Not Reported
Deafness; Deafness;	Enbrel	S		Not Reported
Deafness Transitory;	Enbrel	S		Not Reported
Deafness Transitory;	Enbrel	S		Not Reported
Decreased Appetite;	Methotrexate	S	Unknown	Not Reported
Decreased Appetite;	Methotrexate	S		Not Reported
Dizziness; Dizziness; Drug	Methotrexate	S		Not Reported
Hypersensitivity; Drug	Motrin	S	Unknown	Not Reported
Hypersensitivity; Ear	Motrin	S		Not Reported
Infection; Ear Infection;	Motrin	S		Not Reported
Ear Infection; Eating	Naprosyn	S	Unknown	Not Reported
Disorder; Feeding	Naprosyn	S		Not Reported
Disorder; Feeding	Naprosyn	S		Not Reported
Disorder; Foot Operation;	Plaquenil	S	Oral	Not Reported
Foot Operation; Functional	Sodium Aurothiomalate	S	Intramuscular	Not Reported
Gastrointestinal Disorder;	Sodium Aurothiomalate	S	Oral	Not Reported
Functional Gastrointestinal	Voltaren	S	Unknown	Not Reported
Disorder; Functional	Gold Sodium Thiomalate	S	Unknown	Not Reported
Gastrointestinal Disorder;	Gold Sodium Thiomalate	S		Not Reported
Gastrointestinal Disorder;	Gold Sodium Thiomalate	S		Not Reported
Gastrointestinal Disorder;	Gold Sodium Thiomalate	S		Not Reported
Gastrointestinal Pain;	Aspirin	S	Oral	Not Reported
Gastrointestinal Pain;	Aspirin	S		Not Reported
Gastrointestinal Pain;	Aspirin	S		Not Reported
Headache; Headache;	Aspirin	S		Not Reported
Headache; Hypophagia;	Naproxen	S	Unknown	Not Reported
Hypophagia;				
Musculoskeletal Disorder;				
Musculoskeletal Disorder;				
Musculoskeletal Disorder;				
Nausea; Nausea; Nausea;				
Off Label Use; Pharyngitis;				

Pharyngitis; Pharyngitis; Shoulder Arthroplasty; Shoulder Arthroplasty; Vomiting; Vomiting; Vomiting; Weight Decreased; Weight Decreased	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Diclofenac	S		Not Reported
	Diclofenac	S		Not Reported
	Diclofenac	S		Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S		Not Reported
	Hydroxychloroquine	S		Not Reported
	Hydroxychloroquine	S		Not Reported
	Ascorbic Acid	S	Unknown	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown	Not Reported
	Trimethoprim	S	Unknown	Not Reported
	Acetylsalicylic Acid	S	Unknown	Not Reported
	Apo Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Clopidogrel	S	Unknown	Not Reported
	Apo Asa	S	Unknown	Not Reported
	Apo Diclofenac Ophthalmic	S	Topical	Not Reported
	Vitamin C	S	Unknown	Not Reported
	Ibuprofen	S	Unknown	Not Reported
	Acetylsalicylic Acid W/Clopidogrel	S	Unknown	Not Reported
	Apo-Diclofenac	S	Topical	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Tramadol Hydrochloride	C	Unknown	Not Reported
	Tramadol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	15675837	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573839-00		73 YR	Female	CAN

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

Anxiety Disorder; Confusional State; Hepatic Steatosis; Infection; Knee Operation; Memory Impairment; Nausea; Nightmare; Pain; Polymyalgia Rheumatica; Rheumatoid Arthritis; Visual Impairment; Visual Impairment	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Macrobid	C		Not Reported
	Tylenol	C		Not Reported
	Acetaminophen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	15767354	EXPEDITED (15-DAY)		OT	PHHY2018FR192776		30 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Maternal Exposure During Pregnancy; Premature Baby; Premature Delivery; Premature Rupture Of Membranes	Ursodeoxycholic Acid			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	150 Milligram Daily		Not Reported
	Azathioprine			S	Unknown	2.2 Mg/Kg, Unk		Not Reported
	Azathioprine			S				Not Reported
	Prednisone			S	Unknown	5 Milligram Daily		Novartis
	Prednisone			S				Novartis
	Hydroxychloroquine			S	Unknown	150 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	15855795	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2634312-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported

Arava	S	Oral	For 3 Months	Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Methotrexate Sodium	S	Subcutaneous		Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Methotrexate Sodium	S	Intramuscular		Not Reported
Methotrexate Sodium	S	Subcutaneous		Not Reported
Plaquenil	S	Oral		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not		Not Reported

			otherwise specified)	
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Intramuscular	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Intramuscular	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Intramuscular	Not Reported
	Methotrexate	S	Intramuscular	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	15977831	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-072428		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Osteoporotic	Orencia			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb

Fracture; Spinal Compression Fracture	Actemra	S	Subcutaneous	162 Mg, Qwk		Not Reported
	Simponi	S	Unknown	50 Mg, Q4wk		Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Qwk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Azathioprine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine	C	Unknown	Unk		Not Reported
	Tylenol Arthritis	C	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported
	Xeljanz	C	Unknown	10 Mg, Bid		Not Reported
	Acetaminophen	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	16120764	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044085			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Off Label Use; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Q2wk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Milligram, Bid		Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram		Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown	81 Mg, Qd		Not Reported
	Tiaprofenic Acid			C	Unknown	300 Mg, Qd		Not Reported
	Hydroxychloroquine Sulphate			C	Unknown	200 Milligram, Bid		Not Reported

Leflunomide	C	Oral	20 Milligram, Qd		Not Reported
Methotrexate	C	Subcutaneous	Unk		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	16226842	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110423		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abnormal Loss Of Weight; Alopecia; Arthritis; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Hepatic Enzyme Abnormal; Myocardial Infarction; Rash	Hydroxychloroquine Sulfate			S	Oral	2 Df, Qd		Sanofi
	Leflunomide			S	Oral	1 Df, Qd		Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Metoprolol			C				Not Reported
	Pantoprazole			C				Not Reported
	Ramipril			C				Not Reported
	Rosuvastatin			C				Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Clopidogrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	16232199	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110436		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Cervical Vertebral Fracture; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Interaction; Drug Intolerance; Grip Strength Decreased; Hypophagia; Influenza; Joint Range Of Motion Decreased; Loss Of Consciousness; Malaise; Mobility	Plaquenil			S				Sanofi
	Methotrexate			S				Not Reported
	Arava			S				Sanofi
	Simponi			S				Not Reported
	Humira			S	Subcutaneous			Not Reported

Decreased; Nausea; Nausea; Rheumatoid Arthritis; Upper Limb Fracture; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	16232647	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110439			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Dyspepsia; Food Intolerance; Hepatotoxicity; Rash; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Oral			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			C	Unknown			Not Reported
	Methotrexate			C	Unknown	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	16842729	EXPEDITED (15-DAY)		DS, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3543		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Arthralgia; Arthropathy; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Creatinine Increased;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S				Not Reported

Blood Parathyroid Hormone Decreased; Blood Pressure Systolic Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Decreased Appetite; Diarrhoea; Drug Eruption; Drug Intolerance; Enthesopathy; Erythema; Fatigue; Fear Of Injection; General Physical Health Deterioration; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Insomnia; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Overdose; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Etanercept	S	Unknown		Not Reported
	Etanercept	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Infliximab Hospira	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab Hospira	S	Intravenous (not otherwise specified)		Not Reported
	Ibuprofen	S	Oral	Every 3-4 Hours Regularly	Not Reported
	Ibuprofen	S	Oral		Not Reported
	Ibuprofen	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	2 Times/Wk	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Apo Ibuprofen	S	Oral		Not Reported

Apo-Leflunomide	S	Oral	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Cyclosporine	S	Oral	Not Reported
Apo-Cyclosporine	S	Unknown	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Abatacept	S	Unknown	Not Reported
Stelara	S	Subcutaneous	Not Reported
Stelara	S	Unknown	Not Reported
Golimumab	S	Subcutaneous	Not Reported
Ustekinumab	S	Subcutaneous	Not Reported
Ustekinumab	S	Unknown	Not Reported
Certolizumab Pegol	S	Subcutaneous	Not Reported
Certolizumab Pegol	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Apremilast	S	Oral	Not Reported
Apremilast	S	Unknown	Not Reported
Apremilast	S	Unknown	Not Reported
Cyclosporine	S	Oral	Not Reported
Cyclosporine	S	Unknown	Not Reported
Otezla	S	Oral	Not Reported
Otezla	S		Not Reported
Otezla	S		Not Reported
Ciclosporin	S	Oral	Not Reported
Ciclosporin	S	Unknown	Not Reported
Ciclosporin	S	Unknown	Not Reported

Sulfamethoxazole	S	Oral		Not Reported
Motrin	S	Oral	Every 3-4 Hours Regularly	Not Reported
Motrin	S	Oral		Not Reported
Motrin	S	Oral		Not Reported
Motrin	S	Unknown		Not Reported
Motrin	S	Oral		Not Reported
Motrin	S	Oral		Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Unknown		Not Reported
Simponi	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Alendronate Sodium	S	Unknown	4 Every 1 Week	Not Reported
Codeine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Arava	S	Unknown	Frequency: 1 Every 2 Day	Not Reported
Arava	S	Unknown	Frequency: 1 Every 2 Day	Not Reported
Celebrex	S	Oral		Not Reported
Cosentyx	S	Unknown		Not Reported
Cosentyx	S	Subcutaneous		Not Reported
Rituximab	S	Unknown		Not Reported
Acetaminophen	S	Unknown		Not Reported
Diphenhydramine	S	Unknown		Not Reported
Anolamine Hydrochloride	S	Unknown		Not Reported

[Phenylpropanolamine Hydrochloride]			
Oxycodone	C	Unknown	Not Reported
Oxyneo	C	Unknown	Not Reported
Oxyneo	C	Unknown	Not Reported
Mogadon	C	Unknown	Not Reported
Uloric	C		Not Reported
Colchicine	C		Not Reported
Acide Folique	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Nitrazepam	C	Unknown	Not Reported
Benadryl	C	Unknown	Not Reported
Dexilant	C	Unknown	Not Reported
Gravol	C	Unknown	Not Reported
Febuxostat	C	Unknown	Not Reported
Oxycodone Hydrochloride	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Naproxen	C	Unknown	Not Reported
Cannabis Sativa	C	Unknown	Not Reported
Actonel	C	Unknown	Not Reported
Vitamin D3	C	Unknown	Not Reported
Risedronate Sodium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	16904609	EXPEDITED (15-DAY)		OT	GB-ADVANZ PHARMA-MAPI_00011608			Unknown	GBR

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

Platelet Count Decreased	Humira		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17424304	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5764		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Creatinine Increased; Bone Pain; Decreased Appetite; Drug Ineffective; Dyspnoea; Feeling Hot; Heart Rate Decreased; Loss Of Personal Independence In Daily Activities; Macular Degeneration	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Shingrix			S	Unknown			Not Reported
	Nitro			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17425150	EXPEDITED (15-DAY)		HO, OT	FR-ADVANZ PHARMA-202002000774			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Cell Death; Cholestasis; Dyspnoea; Eosinophil Count Increased; Epidermal Necrosis; Pustular Psoriasis; Pyrexia; Rash; Rash Pustular; Skin Exfoliation; Toxic Skin Eruption	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	2 Dosage Form, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	2 Dosage Form, Qd		Concordia
	Levothyrox			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17461344	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555255		56 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17461703	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1002		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Faeces Discoloured; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Aclasta			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Liver Function Test Abnormal; Malaise; Meniscus Injury; Neuropathy Peripheral; Off Label Use; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Paraplegia; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Disorder; Spinal Stenosis; Treatment Failure; Upper Respiratory Tract Infection	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Tramacet	S	Oral	Not Reported
	Tramacet	S	Unknown	Not Reported
	Amitriptyline	C	Unknown	Not Reported
	Calcium	C	Unknown	Not Reported
	Depo-Medrol	C	Subcutaneous	Not Reported
	Depo-Medrol	C	Intramuscular	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Lorazepam	C	Unknown	Not Reported
	Lyrica	C	Oral	Not Reported
	Metformin	C	Unknown	Not Reported
	Metformin	C	Unknown	Not Reported
	Methylprednisolone Acetate	C	Intramuscular	Not Reported
	Methylprednisolone Acetate	C	Subcutaneous	Not Reported
	Methylprednisolone Acetate	C	Subcutaneous	Not Reported
	Methylprednisolone Acetate	C	Unknown	Not Reported
	Nortriptyline	C	Unknown	Not Reported
	Nortriptyline	C	Unknown	Not Reported
	Nortriptyline Hydrochloride	C	Unknown	Not Reported
	Nortriptyline Hydrochloride	C	Unknown	Not Reported
	Oxycocet	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported

	Risedronate Sodium	C	Unknown	Not Reported
	Tylenol 8 Hr Arthritis Pain	C	Unknown	Not Reported
	Vagifem	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17461752	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1007		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Gait Disturbance; Nerve Compression	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17461763	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1003			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gout; Pneumonia	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Januvia			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17461770	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1019			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Empyema; Musculoskeletal Stiffness; Musculoskeletal Stiffness	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17461789	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1010			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Gastrointestinal Disorder; Hepatitis; Rash	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17461792	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1005			Male	CAN

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

Drug Hypersensitivity; Gastric Disorder; Gastric Haemorrhage; Pain; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Tylenol 8 Hr Arthritis Pain		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17462087	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557138			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17462446	EXPEDITED (15-DAY)		OT	CA-ROCHE-2551186		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety;	Rituxan			S	Intravenous drip	3.0 Years		Not Reported

Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Enbrel	S	Subcutaneous	3.0 Years	Not Reported
	Humira	S	Subcutaneous	Therapy Duration- 3.0 Months, Frequency-Cyclical	Not Reported
	Methotrexate	S	Unknown	Therapy Duration-9.0 Years	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	3.0 Months	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	2.0 Months	Not Reported
	Prednisone	S	Unknown	12.0 Months	Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral	Therapy Duration-2.0 Months	Not Reported
	Xeljanz	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	12.0 Months	Not Reported
	Dexamethasone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17462501	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553927			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported

	Orencia	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17462583	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-015196		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Naproxen			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17462604	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1026		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Anakinra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Unknown	Not Reported
	Adalimumab	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17462721	EXPEDITED (15-DAY)		CA, OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US-000636			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ebstein'S Anomaly; Foetal Exposure During Pregnancy	Hydroxychloroquine			S	Transplacental	400 Milligram, Qd		Ipca
	Warfarin			S	Transplacental	Unk		Ipca
	Belimumab			S	Transplacental	10 Microgram/Kilogram		Not Reported
	Heparin			S	Transplacental	Unk		Not Reported
	Enoxaparin			S	Transplacental	Unk		Not Reported

	Prednisone		S	Transplacental	2.5 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17462766	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189781			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17462854	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3293340-00			Female	CAN

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

Drug Ineffective; Drug Intolerance; Malaise; Multiple Sclerosis; Vomiting	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Cannabis Sativa	C			Not Reported
	Acetaminophen	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17463135	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1020524		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Prednisone			S		1 Df, Qd		Not Reported
	Aspegic /00002701/			S		Unk		Mylan
	Pentoxifylline			S		1 Df, Qd		Mylan
	Kardegic			S		Unk		Mylan
	Plaquenil /00072603/			S		1 Df, Qd		Mylan
	Lovenox			S		Unk		Mylan
	Gestarelle G			S		Unk		Mylan
	Doliprane			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17463410	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189863		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Cough; Disease Progression; Drug Ineffective; Immobile; Malaise	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Celebrex			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Naproxen Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17463951	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553949		60 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17464189	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189738			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Alendronate Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Topical			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Topicort[Desoximetasone]	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17464539	EXPEDITED (15-DAY)		OT	NVSC2020CA045634			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hyperhidrosis; Inappropriate Schedule Of Product Administration; Nausea; Rheumatoid Arthritis	Estradot			S	Transdermal	1 Df, Qw		Novartis
	Leflunomide			S	Unknown	20 Mg, Q24h		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	2 Df, Qd		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17464549	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020085116			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S		25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Actemra			S		Unk		Not Reported
	Apo-Leflunomide			S		20 Mg, 1x/Day		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg, 2x/Day		Not Reported

	Orencia	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	C		Unk	Not Reported
	Wellbutrin	C		Unk	Not Reported
	Xeljanz	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17464712	NON-EXPEDITED		OT	NVSC2020US051130		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Liver Injury; Pyrexia	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17465228	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189663		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Oedema Peripheral; Pain	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17465230	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189751			Female	CAN

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

Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Prednisone	S	Oral	Actavis
	Actemra	S	Subcutaneous	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17465393	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3293377-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hepatic Enzyme Increased; Pyrexia; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17483085	DIRECT	Y	OT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Hydroxychloroquine			S	Oral		1 MTH	Dr Reddys

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	15630828	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105531		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Endocervical			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Dorzolamide Hcl Timolol Maleate			C	Unknown	2 Df, Qd		Not Reported

Ergocalciferol	C	Unknown	Unk, Qd		Not Reported
Estradiol	C	Unknown			Not Reported
Estrogel	C	Unknown	1 Df= 0.6 Percent 3 Times, Qd		Not Reported
Furosemide	C	Unknown	40 Mg, Qd		Not Reported
Morphine	C	Unknown			Not Reported
Potassium Chloride	C	Unknown	1500 Mg, Qd		Not Reported
Valsartan	C	Unknown	320 Mg, Qd		Not Reported
Xalatan	C	Unknown	50 Mg, Qd		Not Reported
Zingiber Officinale	C	Unknown	500 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	15856062	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633852-00			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	15930670	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2655655-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Metals; Arthralgia; Arthropathy; Blood Cholesterol Increased; Contraindicated Product Administered; Gastric Disorder; Granuloma; Pain In Extremity; Pruritus; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased; Skin Wrinkling; Spinal Osteoarthritis; Therapeutic Product Effect Decreased; Thyroid Disorder	Humira			S	Subcutaneous			Not Reported
	Celebrex			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	16231133	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110410			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug Ineffective; Drug Ineffective; Juvenile Idiopathic Arthritis; Polyarthritis	Hydroxychloroquine Sulfate			S		Unk Unk, Unk		Sanofi
	Chloroquine (Salt Not Specified)			S	Oral	400 Mg, Qd		Sanofi
	Methotrexate			S		25 Mg, Qw		Not Reported
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Prednisone			C	Oral	7 Mg, Qd		Not Reported
	Etanercept			C		50 Mg, Qw		Not Reported
	Cosentyx			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17041158	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201812-004125			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment; Spinal Compression Fracture; Visual Field Defect	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Prednisolone			S	Oral	8 Mg, Qd		Not Reported
	Prednisolone			S	Oral	7 Mg, Qd		Not Reported
	Prednisolone			S	Oral	6 Mg, Qd		Not Reported
	Prednisolone			S	Oral	5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	9 Mg, Qd		Not Reported
	Prednisolone			S	Oral	10 Mg, Qd		Not Reported
	Prednisolone			S	Oral	12.5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	15 Mg, Qd		Not Reported
	Prednisolone			S	Oral	5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	6 Mg, Qd		Not Reported
	Prograf			S	Oral	2 Mg, Qd		Not Reported
	Ulcerlmin			C		Unk		Not Reported
	Bonoteo			C		50 Mg, Q4w		Not Reported
	Diovan			C		Unk		Not Reported
	Takepron			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465134	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555249			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Rituximab			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Levothyroxine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465184	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557142			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Mobility Decreased; Osteomyelitis; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Hydrocortisone Valerate			C	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Lyderm [Fluocinonide]			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sodium Aurothiomalate			C	Unknown			Not Reported
	Sodium Aurothiomalate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465310	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020085748		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown			Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465380	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202002000971			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiovascular Disorder; Menorrhagia; Surgery; Uterine Haemorrhage	Hydroxychloroquine			S	Unknown			Concordia
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465478	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557866			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea;	Rituxan			S	Intravenous (not			Not Reported

Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance			otherwise specified)		
	Arava	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465479	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557916		42 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465556	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557855			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Drug Ineffective; Infection; Insomnia; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465574	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557140		60 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465647	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3293370-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Colitis Ulcerative; Contraindicated Product Administered; Drug Ineffective; Effusion; Rheumatoid Factor Positive; Synovitis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465649	EXPEDITED (15-DAY)		OT	CA-ROCHE-2554327			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			C	Subcutaneous			Not Reported
	Diclofenac			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

	Cortisone Acetate	C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465691	EXPEDITED (15-DAY)		HO	CA-ROCHE-2557122			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Rheumatoid Arthritis; Weight Increased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Morphine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Indomethacin [Indometacin]			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465831	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1040		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Musculoskeletal Pain; Pain In Extremity; Pancreatic Carcinoma; Peripheral Swelling; Rheumatoid Arthritis;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Splenectomy; Swelling; Therapeutic Product Effect Decreased	Humira		S	Subcutaneous	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Simponi		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465832	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1013			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Intolerance; Haematochezia; Hepatic Enzyme Increased; Joint Swelling; Muscle Spasms; Nausea; Neuropathy Peripheral; Rash; Skin Burning Sensation	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Atorvastatin Calcium			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Plaquenil S			S	Oral			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Asa Ec			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Vitamin D3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465840	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189900			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Diclofenac			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

	Cimzia Single-Use Pre-Filled Syringe	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Reactine [Cetirizine]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466009	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189885			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Diclofenac			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Reactine (Cetirizine)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466010	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189902			Female	CAN

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

	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466020	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1189746		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Asthenia; Astigmatism; Balance Disorder; Blood Glucose Increased; Cataract; Dizziness; Fall; Fatigue; Feeling Hot; Gastric Disorder; Gastrointestinal Disorder; Head Discomfort; Headache; Hot Flush; Hypersomnia; Hypnotherapy; Incorrect Dose Administered; Insomnia; Irritable Bowel Syndrome; Kidney Infection; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Pain; Nasal Congestion; Nausea; Neck Pain; Nephrolithiasis; Oropharyngeal Discomfort; Pain; Pain In Extremity; Pruritus; Raynaud'S Phenomenon; Sepsis; Sinusitis; Sleep Apnoea Syndrome;	Prednisone Acetate			S	Unknown			Actavis
	Prednisone Acetate			S	Unknown			Actavis
	Prednisone Acetate			S	Unknown			Actavis
	Fentanyl			S	Unknown			Cephalon
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil Hydrochloride			S	Unknown			Teva
	Belimumab			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Gravol			C				Not Reported
	Neurontin			C	Unknown			Not Reported
	Neurontin			C				Not Reported

Stress; Therapeutic Product Effect Decreased; Toxicity To Various Agents; Upper Respiratory Tract Congestion; Urinary Tract Infection; Vision Blurred; Visual Impairment; Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466037	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189912		71 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral; Drug Ineffective	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Tofacitinib			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466041	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189903			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Pulmonary Toxicity	Prednisone			S	Unknown	5 Mg		Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported

	Sulfasalazine		S	Unknown	2 Gram Daily;	Not Reported
	Xeljanz		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466207	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555847			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Drug Ineffective	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466449	EXPEDITED (15-DAY)		OT	CA-ROCHE-2551554		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous	9.0 Months		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	9.0 Months		Not Reported

Enbrel	S	Unknown	4.0 Years		Not Reported
Humira	S	Subcutaneous	4.0 Years		Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Infliximab	S	Intravenous (not otherwise specified)	2.0 Years		Not Reported
Methotrexate	S	Unknown			Not Reported
Methotrexate	S	Unknown			Not Reported
Orencia	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Pregabalin	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	2.0 Years		Not Reported
Simponi	S	Unknown			Not Reported
Sodium Aurothiomalate	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466577	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555862		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Nasopharyngitis; Viral Upper Respiratory Tract Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

				otherwise specified)	
	Simponi		S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466730	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-06445			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown	Unknown		Not Reported

	Triamcinolone Hexacetonide	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466855	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189699			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466876	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189709		43 YR	Female	CAN

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

Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Prednisone	S	Unknown		Actavis
	Prednisone	S	Unknown		Actavis
	Alendronate Sodium	S	Oral		Actavis
	Diclofenac Sodium	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	10 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not		Not Reported

			otherwise specified)	
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Topicort	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Atasol [Paracetamol]	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466992	EXPEDITED (15-DAY)		DS	CA-ROCHE-2557149		42 YR	Female	CAN

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

	Prednisone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17467082	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2016-05191		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury	Hydroxychloroquine			S	Unknown	Unk Unk,Unk,Unknown		Lupin
	Prednisone			C	Unknown	Unk Unk,Unk,Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17467235	NON-EXPEDITED		DE, OT	NVSC2020US047643		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Overdose; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	6 G		Novartis
	Ibuprofen			S	Unknown	200 Mg		Not Reported
	Naproxen			S	Unknown	750 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17467282	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2020084507		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Musculoskeletal Disorder	Methotrexate Sodium			S				Pfizer
	Sulfasalazine			S				Pfizer
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17467333	NON-EXPEDITED			US-PFIZER INC-2020086812		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

	Xeljanz Xr			C	Oral	11 Mg, Daily			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17467359	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020083924			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Intolerance; Finger Deformity; Foot Deformity; Gait Disturbance; Infection; Pancytopenia	Methotrexate Sodium			S	Oral	7.5 Mg, Once Weekly		Pfizer
	Humira			S	Subcutaneous	40 Mg, Every 2 Weeks		Not Reported
	Leflunomide			S		20 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17467817	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00009890		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Hydroxychloroquine			S	Oral	Unknown		Unknown
	Cyclobenzaprine			S	Oral	Unknown		Unknown
	Esomeprazole			S	Oral	Unknown		Unknown
	Clindamycin			S	Oral	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17468132	DIRECT		OT				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Plaquenil			S				Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17469402	EXPEDITED (15-DAY)		OT	NVSC2020DE049601		24 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Lupus Nephritis	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17470523	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-2008857US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Chest Pain; Respiratory Distress; Tachycardia; Unevaluable Event	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	12769741	EXPEDITED (15-DAY)		OT	CA-ROCHE-1833370			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Intentional Product Use Issue; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Synovitis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Unknown			Not Reported

	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Varicella Zoster Vaccine Live	S	Unknown	Not Reported
	Cortisone	C	Oral	Not Reported
	Diclofenac	C	Oral	Not Reported
	Diclofenac	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C		Not Reported
	Desoximetasone	C	Oral	Not Reported
	Desoximetasone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	14775650	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018158011			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Weekly (Qwk)		Pfizer
	Sulfasalazine			S	Unknown	1 Gram, Bid		Pfizer
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, 1x/Day (Qd)		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	14921372	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043586			Male	CAN

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

Bronchitis; Burning Sensation; C-Reactive Protein Increased; Colitis; Diarrhoea; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nausea; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting; White Blood Cell Count Decreased	Orencia	S	Subcutaneous	125 Milligram	Bristol Myers Squibb
	Orencia	S	Unknown		Bristol Myers Squibb
	Actemra	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Enbrel	S	Unknown		Not Reported
	Methotrexate	S	Oral	15 Milligram	Not Reported
	Methotrexate	S	Oral	20 Milligram	Not Reported
	Cosentyx	S	Unknown	150 Milligram	Not Reported
	Otezla	S	Oral	30 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	400 Milligram	Not Reported
	Sulfasalazine	C	Unknown	1 Gram, Bid	Not Reported
	Hydroxychloroquine	C	Unknown	200 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	15218809	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1004		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Creatinine Decreased; Blood Pressure Diastolic Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Contusion; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Intra-arterial			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported

Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Heart Rate Decreased; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Joint Swelling; Knee Arthroplasty; Live Birth; Malignant Melanoma; Maternal Exposure During Pregnancy; Monocyte Count Increased; Musculoskeletal Disorder; Musculoskeletal Stiffness; Neutrophil Count Increased; Off Label Use; Pain; Pemphigus; Pericarditis; Product Complaint; Product Use Issue; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Seborrhoeic Keratosis; Sinusitis; Swelling; Synovial Disorder; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Wound	Methotrexate (Trade Name Unknown)	S	Subcutaneous	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Oral	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Fosamax	S	Unknown	Not Reported
	Fosamax	S	Subcutaneous	Not Reported
	Fosamax	S	Intracavernous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported

Humira	S	Subcutaneous	Cyclic	Not Reported
Humira	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Subcutaneous		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Intravenous (not otherwise specified)		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Subcutaneous		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Unknown		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported

Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Unknown	Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Cimzia	S	Unknown	Not Reported
Cimzia	S	Unknown	Not Reported
Cimzia	S	Unknown	Not Reported
Cimzia	S	Unknown	Not Reported
Cortisone Acetate	S	Oral	Not Reported
Cortisone Acetate	S	Oral	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Cortisone Acetate	S	Topical	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Subcutaneous	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Not Reported

Apo-Prednisone	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Cetirizine Hydrochloride	S	Unknown		Not Reported
Cetirizine Hydrochloride	S	Oral		Not Reported
Cetirizine Hydrochloride	S	Unknown		Not Reported
Desoximetasone	S	Oral		Not Reported
Desoximetasone	S	Unknown		Not Reported
Apo-Folic Acid	S	Unknown		Not Reported
Apo-Folic Acid	S	Unknown		Not Reported
Apo-Folic Acid	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Cetirizine	S	Unknown		Not Reported
Cetirizine	S	Unknown		Not Reported
Cetirizine	S	Oral		Not Reported
Cetirizine	S	Unknown		Not Reported
Cetirizine	S	Unknown	5mg/5 Ml	Not Reported
Sulfathalidine	S	Unknown		Not Reported
Plaquenil	S	Oral		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Diclofenac Sodium	S	Unknown		Not Reported
Diclofenac Sodium	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
Alendronate Sodium	S	Oral		Not Reported
Alendronate Sodium	S	Unknown		Not Reported
Cortisone	S	Oral		Not Reported

Cortisone	S	Unknown		Not Reported
Topicort (Desoximetasone)	S	Subcutaneous		Not Reported
Topicort (Desoximetasone)	S	Unknown		Not Reported
Topicort (Desoximetasone)	S	Oral		Not Reported
Topicort (Desoximetasone)	S	Other		Not Reported
Apo-Sulfasalazine	S	Unknown		Not Reported
Golimumab	S	Unknown		Not Reported
Golimumab	S	Intravenous (not otherwise specified)		Not Reported
Golimumab	S	Subcutaneous		Not Reported
Stelara	S	Unknown		Not Reported
Paracetamol	S	Unknown		Not Reported
Hydrocortisone Acetate	S	Subcutaneous		Not Reported
Hydrocortisone Acetate	S	Unknown		Not Reported
Hydrocortisone Acetate	S	Oral		Not Reported
Hydrocortisone Acetate	S	Other		Not Reported
Leflunomide	S	Oral		Not Reported
Leflunomide	S	Unknown		Not Reported
Zyrtec	S	Unknown	5 Mg/5ml	Not Reported
Zyrtec	S	Unknown		Not Reported
Sarilumab	S	Unknown		Not Reported
Cetirizine Hydrochloride W/Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Cetirizine Hydrochloride W/Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Cetirizine Hydrochloride W/Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Salazopyrin	S	Unknown		Not Reported
Salazopyrin	S	Unknown		Not Reported

Salazopyrin	S	Unknown	Not Reported
Salazopyrin	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Cosentyx	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Atasol	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Diclofenac	C	Unknown	Not Reported
Ibuprofen	C	Unknown	Not Reported
Lisinopril	C	Unknown	Not Reported
Vitamin D3	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Omega [Omeprazole]	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Vitamin C	C	Unknown	Not Reported
Ascorbic Acid	C	Unknown	Not Reported
Omeprazole	C	Unknown	Not Reported
Omeprazole Sodium	C	Unknown	Not Reported
Prednisolone	C	Unknown	Not Reported
Acetaminophen	C	Oral	Not Reported
Acetaminophen	C	Oral	Not Reported
Curamin	C	Unknown	Not Reported
Diphenhydramine Hcl	C	Oral	Not Reported
Leucovorine	C	Unknown	Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported

	Vitamin C		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	15333538	NON-EXPEDITED		HO, OT	US-AMGEN-USASP2018118188		66 YR	Male	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	15935754	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656874-00			Female	CAN

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

	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	16079910	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-05962		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

Prednisone	S	Oral			Not Reported
Prednisone	S	Unknown			Not Reported
Sulfasalazine	S	Oral			Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)			Not Reported
Tocilizumab	S	Unknown			Not Reported
Triamcinolone	S	Other	Unknown		Not Reported
Triamcinolone	S	Unknown	Unknown		Not Reported
Triamcinolone Hexacetonide	S	Unknown	Unknown		Not Reported
Triamcinolone Hexacetonide	S	Other	Unknown		Not Reported
Apo-Naproxen	S	Unknown	Unknown		Not Reported
Apo-Prednisone	S	Oral			Not Reported
Apo-Prednisone	S	Oral			Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unknown		Not Reported
Hydroxychloroquine	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	16539596	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-063602			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, 2 Every Day 1		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, 2 Every 1 Day		Not Reported
	Xeljanz			C	Oral	5 Milligram., 2 Every Day 1		Not Reported

	Hydroxychloroquine Sulphate	S	Unknown	200 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	16891755	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-29184			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Infliximab			S	Unknown	Unknown (Route Of Admin: Intracardiac)		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown (Solution)		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown (Powder For Solution Intravenous)		Not Reported
	Amlodipine			C	Unknown	Unknown		Not Reported
	Xeljanz			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17227197	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0002		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Joint Swelling; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Prevnar 13			S	Intramuscular	Single Dose		Not Reported
	Depo-Medrol With Lidocaine			S	Unknown			Not Reported

Enbrel	S	Subcutaneous	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Azathioprine Sodium	S	Oral	Not Reported
Humira	S	Subcutaneous	Not Reported
Ketoprofen	S	Topical	Not Reported
Leucovorin Calcium	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil	S	Subcutaneous	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate Sodium	C	Unknown	Not Reported
Lederle Leucovorin	C	Unknown	Not Reported
Shingrix	C	Unknown	Not Reported
Corticosteroids	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17431251	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3275137-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspepsia; Joint Swelling; Therapy Partial Responder	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17470756	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555241		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Mass Excision; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17471374	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553868		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous drip			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Gold	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Imuran [Azathioprine]	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17471381	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202002001039			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alopecia; Balance Disorder; Cervical Radiculopathy; Condition Aggravated; Contusion; Cutaneous Lupus Erythematosus; Dehydration; Depressed Mood; Depression; Diarrhoea; Fatigue; Gastritis; Gastroenteritis Viral; Grip Strength Decreased; Headache; Hot Flush; Limb Discomfort; Multiple Sclerosis Relapse; Nausea; Rash; Spinal Pain; Toothache; Vision Blurred; Visual Impairment	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Aubagio			S	Oral	7 Mg, Qd		Not Reported
	Aubagio			S	Oral	14 Mg, Qd		Not Reported
	Cymbalta			C		Unk		Not Reported
	Cymbalta			C				Not Reported
	Ritalin			C		Unk		Not Reported
	Orsythia			C		Unk		Not Reported
	Omeprazole			C		Unk		Not Reported
	Vitamin D3			C		Unk		Not Reported
	Cyanocobalamin			C		Unk		Not Reported
	Trazodone			C		Unk		Not Reported
	Trazodone			C				Not Reported
	Zanaflex			C		Unk		Not Reported

Carbamazepine	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17471519	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202002001042			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Haemorrhoids; Rectal Haemorrhage	Hydroxychloroquine			S	Unknown	200 Mg		Concordia
	Leflunomide			S	Unknown	20 Mg		Not Reported
	Methotrexate			C		Unk		Not Reported
	Tofacitinib			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17471549	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553830		84 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17471598	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2020-ES-1192454		25 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Epidermal Necrolysis	Hidroxicloroquina			S	Unknown			Teva
	Deflazacort			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17471689	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1190410			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Codeine			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown	70 Mg, 4 Every 1 Week		Actavis
	Alendronate Sodium			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous	15 Mg, 4 Every 1 Week		Barr
	Methotrexate			S	Unknown	12 Mg, 4 Every 1 Week		Barr
	Methotrexate			S	Unknown	12.5 Mg, 4 Every 1 Week		Barr
	Methotrexate			S	Subcutaneous	40 Milligram Daily; 10 Mg, 4 Every 1 Week		Barr
	Methotrexate			S	Subcutaneous	17.5 Mg, 4 Every 1 Week		Barr
	Methotrexate			S	Unknown	10 Mg, 4 Every 1 Week		Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	2000 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Ciclosporin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17471818	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-014443		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			S	Oral	50 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Estradiol			C	Unknown			Not Reported
	Levaquin			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Xalatan			C	Ophthalmic			Not Reported
	Baclofen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17472124	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1045			Female	CAN

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

	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17472131	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1057		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Meloxicam	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17472177	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557127		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17472274	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1190487			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Loss Of Consciousness	Ibuprofen			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Aleve			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17472279	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1069			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Intolerance; Finger Deformity; Foot Deformity; Gait Disturbance; Infection; Pancytopenia	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17472285	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557159		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Dermatomyositis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Intentional Product Use Issue; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Pain; Thrombosis; Uterine Disorder; Weight Increased	Rituxan			S	Intravenous drip			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Metformin Hydrochloride			S	Unknown			Not Reported
	Metformin Hydrochloride			S				Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported
	Xarelto			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17473105	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-		30 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Mobicox			S	Unknown			Boehringer Ingelheim
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17473784	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2016M1049280		62 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17476461	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020086707		79 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17479336	EXPEDITED (15-DAY)		DE	FR-MYLANLABS-2020M1022918		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Drug Interaction; Electrocardiogram Qt Prolonged	Sotalol			S	Oral	80 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17480167	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-06411			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	13667464	EXPEDITED (15-DAY)		OT	CA-ROCHE-1950692		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Malaise; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 3 Months		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 7 Months		Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 7		Not Reported

Arthritis; Walking Aid User				Months	
	Hydroxychloroquine Sulfate	S	Unknown	Therapy Duration: 2 Years	Not Reported
	Infliximab	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Therapy Duration: 10 Months	Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Therapy Duration: 2 Years	Not Reported
	Atorvastatin	C	Unknown		Not Reported
	Pantoprazole	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	15384083	EXPEDITED (15-DAY)		LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-082847		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Dysphonia; Dyspnoea; Intentional Product Use Issue; Odynophagia; Off Label Use; Rheumatoid Arthritis; Stridor	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Golimumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	16064781	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05865		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hair Follicle Tumour Benign; Off Label Use;	Infliximab			S	Unknown	Unknown		Not Reported

Product Use In Unapproved Indication	Infliximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Etanercept	S	Unknown	Unknown	Not Reported
	Acetazolamide	S	Unknown	Unknown	Not Reported
	Acetazolamide	S			Not Reported
	Alendronic Acid	S	Unknown	Unknown	Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Calcium Carbonate	S	Unknown	Unknown	Not Reported
	Ciclosporin	S	Unknown	Unknown	Not Reported
	Ciclosporin	S			Not Reported
	Ciclosporin	S			Not Reported
	Ferric Hydroxide Polymaltose Complex	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Leflunomide	S			Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Calcium	S	Unknown	Unknown	Not Reported
	Alendronate Sodium	S	Unknown	Unknown	Not Reported
	Alendronate	C	Unknown	Unknown	Not Reported
	Alendronate	C	Unknown	Unknown	Not Reported
	Calcium	C	Unknown	Unknown	Not Reported
	Cyclosporin A	C	Unknown	Unknown	Not Reported
	Cyclosporine	C	Unknown	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Unknown	Not Reported
	Iron	C	Unknown	Unknown	Not Reported
	Mtx	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	16079923	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-05880			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Naproxen			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Triamcinolone Acetonide			S	Intra-articular	Suspension Intra-Articular, Unknown		Not Reported
	Triamcinolone Acetonide			S	Unknown	Unknown		Not Reported
	Triamcinolone Acetonide			S				Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not			Not Reported

				otherwise specified)		
	Humira		S	Subcutaneous	Solution Subcutaneous, Unknown	Not Reported
	Naproxen		S	Unknown	Unknown	Not Reported
	Prednisone		S	Oral		Not Reported
	Prednisone		S	Oral		Not Reported
	Triamcinolone		S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	16082145	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-06072			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported

Prednisone	S	Oral			Not Reported
Sulfasalazine	S	Oral			Not Reported
Triamcinolone	S	Unknown	Unknown		Not Reported
Triamcinolone	S	Subcutaneous			Not Reported
Hydroxychloroquine	S	Oral			Not Reported
Hydroxychloroquine	S	Oral			Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Apo-Naproxen	S	Unknown	Unknown		Not Reported
Apo-Prednisone	S	Oral			Not Reported
Humira	S	Subcutaneous	Unknown		Not Reported
Triamcinolone Acetonide	S	Unknown			Not Reported
Triamcinolone Acetonide	S				Not Reported
Triamcinolone Acetonide	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	16481525	EXPEDITED (15-DAY)		DS, HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-16011		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy;	Infliximab			S	Oral	Unknown		Not Reported
	Alendronate Sodium			S	Unknown	Unknown		Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown	Unknown		Not Reported
	Apo-Ibuprofen			S	Oral	Unknown		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Apremilast			S	Unknown			Not Reported
	Apremilast			S	Unknown	Unknown		Not Reported
	Apremilast			S	Unknown			Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported

Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Cimzia	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Unknown, Solution	Not Reported
	Codeine	S	Unknown	Unknown	Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Unknown	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Ibuprofen	S	Oral		Not Reported
	Ibuprofen	S	Oral	Unknown	Not Reported
	Ibuprofen	S	Oral	Unknown	Not Reported
	Ibuprofen	S	Oral		Not Reported
	Leflunomide	S	Oral	Unknown	Not Reported
	Leflunomide	S	Oral	Unknown	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported

Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Unknown		Not Reported
Motrin	S	Oral		Not Reported
Motrin	S	Oral	Unknown	Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Orencia	S	Subcutaneous	Unknown	Not Reported
Orencia	S			Not Reported
Otezla	S	Unknown	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Remicade	S	Unknown	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Unknown		Not Reported
Simponi	S	Subcutaneous	Unknown, Solution	Not Reported
Stelara	S	Subcutaneous	Unknown, Solution	Not Reported
Sulfasalazine	S	Endocervical	Unknown	Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Benadryl	C	Unknown	Unknown	Not Reported
Colchicine	C	Oral	Unknown	Not Reported
Colchicine	C	Oral	Unknown	Not Reported

	Colchicine	C	Unknown	Unknown	Not Reported
	Dexilant	C	Unknown	Delayed Release Capsule	Not Reported
	Dexilant	C	Unknown	Unknown	Not Reported
	Dexilant	C	Oral	Unknown	Not Reported
	Febuxostat	C	Unknown	Unknown	Not Reported
	Folic Acid	C	Unknown	Unknown	Not Reported
	Gravol	C	Unknown	Unknown	Not Reported
	Mogadon	C	Oral		Not Reported
	Mogadon	C	Oral		Not Reported
	Nitrazepam	C	Unknown		Not Reported
	Nitrazepam	C	Unknown		Not Reported
	Nitrazepam	C	Oral		Not Reported
	Oxycodone	C	Unknown	Unknown	Not Reported
	Prednisone	C	Unknown	Unknown	Not Reported
	Uloric	C	Unknown		Not Reported
	Uloric	C	Unknown		Not Reported
	Uloric	C	Oral	Unknown	Not Reported
	Xeljanz	C	Unknown	Unknown	Not Reported
	Alendronate Sodium	C	Unknown		Not Reported
	Alendronate Sodium	C	Unknown		Not Reported
	Ciclosporin	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17345827	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-02545		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product	Etanercept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Allopurinol			S	Unknown	Unknown		Not Reported

Administered; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Product Complaint; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Amitriptyline	S	Unknown	Unknown	Not Reported
	Amitriptyline	S	Unknown	Unknown	Not Reported
	Amitriptyline Hydrochloride/Perphenazine	S	Unknown	Unknown	Not Reported
	Apo-Azathioprine	S	Unknown	Unknown	Not Reported
	Apo-Diclo	S	Unknown	Unknown, Tablet (Enteric Coated)	Not Reported
	Apo-Diclofenac	S	Topical	Unknown, Solution Topical	Not Reported
	Apo-Leflunomide	S	Unknown	Unknown	Not Reported
	Apo-Naproxen	S	Unknown	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Unknown	Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Arthrotec	S	Unknown	Unknown	Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Celebrex	S	Unknown	Unknown	Not Reported
	Celebrex	S	Unknown	Unknown, Capsule, Hard	Not Reported
	Celecoxib	S	Unknown	Unknown	Not Reported
	Celecoxib	S			Not Reported
	Diclofenac	S	Unknown	Unknown	Not Reported
	Diclofenac Sodium	S	Unknown	Unknown	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Lyrica	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Parenteral	Unknown	Not Reported

Methotrexate	S	Oral	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Unknown	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Methotrexate	S	Unknown	Unknown	Not Reported
Misoprostol	S	Unknown	Unknown	Not Reported
Naprosyn	S	Unknown	Unknown	Not Reported
Naproxen	S	Unknown	Unknown	Not Reported
Nifedipine	S	Unknown	Unknown	Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Orencia	S	Subcutaneous		Not Reported
Prednisone	S	Unknown	Unknown	Not Reported
Pregabalin	S	Unknown	Unknown	Not Reported
Pregabalin	S	Unknown	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Unknown	Unknown	Not Reported
Winpred	S	Unknown	Unknown	Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Unknown		Not Reported
Xeljanz	S	Oral		Not Reported
Apo-Amitriptyline	S	Unknown	Unknown	Not Reported
Diclofenac Potassium	S	Unknown	Unknown	Not Reported
Tofacitinib	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17477277	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557130		59 YR	Female	CAN

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

Fibromyalgia; Nasal Congestion; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection				otherwise specified)	
	Arava		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17477335	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557847			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not			Not Reported

						otherwise specified)				
			Simponi		S	Subcutaneous				Not Reported
			Simponi		S	Subcutaneous				Not Reported
			Plaquenil [Hydroxychloroquine Sulfate]		C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17477359	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557849		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspepsia; Liver Function Test Increased; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown	3.0 Months		Not Reported
	Enbrel			S	Subcutaneous	8.0 Years		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown	14.0 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17477823	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-06466			Unknown	CAN

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

Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Unknown (Solution)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Naproxen	S	Unknown	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Triamcinolone	S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17477873	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-06742			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	Unknown (Solution Subcutaneous)		Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Naproxen	S	Unknown	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Prednisone	S	Oral			Not Reported
	Prednisone	S	Oral			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Unknown (Suspension Intra-Articular)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17477939	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-06751			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S				Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Arava			S				Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Azathioprine			S				Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Ciclosporin			S				Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre-Filled Syringe, Solution Subcutaneous		Not Reported
	Cimzia			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported

	Gold	S	Unknown	Unknown	Not Reported
	Gold	S			Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S			Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S			Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17479823	EXPEDITED (15-DAY)		OT	NVSC2020AU053402		40 YR	Female	AUS

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	Cyclical		Not Reported
	Enbrel			S	Unknown			Not Reported

Apo-Leflunomide	S	Oral			Not Reported
Methotrexate	S	Unknown			Not Reported
Methotrexate	S	Unknown			Not Reported
Orencia	S	Unknown			Not Reported
Plaquenil	S	Oral			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Cyclical		Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Leflunomide	S	Unknown			Not Reported
Leflunomide	S	Unknown			Not Reported
Sulfasalazine	C				Not Reported
Wellbutrin	C	Oral	Modified-Release Tablet		Not Reported
Xeljanz	C				Not Reported
Bupropion	C				Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Malaise; Multiple Sclerosis; Nausea; Vomiting	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily	Humira			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported

Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Treatment Failure	Apo-Leflunomide			S	Oral	Unk		Apotex
	Apo-Hydro			S	Unknown	Unk		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Hydrochlorothiazide			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk (Once In Every Two Moths)		Not Reported
	Humira			S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	15848950	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633442-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

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

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

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

Sulfasalazine	S		1000 Mg, Qd	Pfizer
Sulfasalazine	S		3000 Mg, Qd	Pfizer
Erelzi	S	Unknown	50 Mg, Qw	Not Reported
Hydroxychloroquine	S		250 Mg, Unk	Not Reported
Hydroxychloroquine	S		250 Mg, Unk	Not Reported
Leflunomide	S		Unk	Not Reported
Leflunomide	S		20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Unk	Not Reported
Leflunomide	S		Unk	Not Reported

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

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

Cataract; Gastrointestinal Disorder; Headache; Nausea; Urinary Tract Infection	Prednisolone		S	Unknown	Initial Dose Not Stated	Actavis
	Prednisolone		S	Unknown	20 Milligram Daily; The Dose Was Tapered Further	Actavis
	Sulfasalazine		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Cefradine		C	Unknown		Not Reported
	Amoxicillin		C	Unknown		Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Musculoskeletal Disorder; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cartilage Atrophy; Drug Ineffective; Joint Swelling; Nausea; Nephrotic Syndrome; Periorbital Oedema; Renal Disorder; Skin Erosion; Therapeutic Product Effect Decreased; Wrist Deformity	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease;	Mobicox			S	Unknown			Boehringer Ingelheim

Pain; Rheumatoid Arthritis	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Methotrexate		S	Unknown	Solution	Not Reported
	Orencia		C	Unknown		Not Reported

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis;	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S				Novartis

Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S			Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S			Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive	Ilaris			S	Subcutaneous	Unk		Novartis

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein	Rituxan			S	Intravenous (not			Not Reported

Increased; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling				otherwise specified)	
	Sulfasalazine		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lupus-Like Syndrome; Maternal Exposure During Pregnancy	Hydralazine Hydrochloride			S		10 Milligram Per Day		Heritage
	Hydralazine Hydrochloride			S		60 Milligram Per Day		Heritage
	Hydrochlorothiazide			S		Unk		Heritage
	Meloxicam			S		15 Milligram Daily		Heritage
	Meloxicam			S				Heritage
	Sulfasalazine			S		2 Gram, Bid		Heritage
	Sulfasalazine			S				Heritage
	Dicloxacillin			S		500 Milligram, Three Doses Over A 12-Hour Period		Not Reported
	Hydroxychloroquine			S		400 Milligram Per Day		Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisone			S		7.5 Milligram Daily		Not Reported
	Prednisone			S		20 Milligram Daily		Not Reported
	Naproxen			C		Daily		Not Reported
	Naproxen			C				Not Reported

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

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

	Orencia	S	Subcutaneous	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	11999787	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1618751		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cough; Drug Hypersensitivity; Fatigue; Fatigue; Immune System Disorder; Infusion Related Reaction; Nasopharyngitis; Oxygen Saturation Decreased; Oxygen Saturation Decreased; Pneumonia; Pneumonia Fungal; Pyrexia; White Blood Cell Count Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Diphenhydramine Hcl			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Pregabalin			C				Not Reported
	Rosuvastatin			C				Not Reported
	Aas			C				Not Reported
	Perindopril			C	Unknown			Not Reported
	Dexilant			C				Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C				Not Reported
	Actonel			C				Not Reported
	Methotrexate			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Docusate			C				Not Reported
	Hydromorphone			C				Not Reported
	Calcium			C				Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	12770684	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076867		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Bone Hypertrophy; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Intentional Product Use Issue; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Off Label Use; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Q4wk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	1 Dosage Form, Qwk		Bristol Myers Squibb
	Oxycontin			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	1 Dosage Form, Qwk		Not Reported
	Fentanyl			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2.5 Gram, Qd		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, Qmo		Not Reported
	Actemra			S	Oral			Not Reported
	Nortriptyline Hydrochloride			S	Oral	10 Milligram, Qh		Not Reported
	Myochrysine			S	Intramuscular	50 Mg, Q3wk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Apo-Gabapentin			S	Oral	100 Milligram, Bid		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Celecoxib			S	Oral			Not Reported
	Apo Celecoxib			S	Oral			Not Reported
	Xeljanz			S	Oral	5 Milligram, Qd		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Fentanyl Matrix			S	Unknown			Not Reported
	Nortriptyline Hydrochloride;Perphenazine			S	Oral	10 Milligram, Qd, Cyclical		Not Reported
	Gabapentin			S	Oral	100 Mg, Bid		Not Reported
	Acetaminophen W/Oxycodone			C	Unknown			Not Reported

Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Qmo	Not Reported
Aclasta	C	Unknown	488 Milligram, Qmo	Not Reported
Actonel	C	Unknown	36 Mg, Qwk	Not Reported
Ascorbic Acid	C	Unknown		Not Reported
Biotin	C	Unknown		Not Reported
Calcium	C	Unknown	Unk Unk, Qd	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Milligram, Bid	Not Reported
Diphenoxylate Hydrochloride And Atropine Sulfate	C	Unknown		Not Reported
Diphenoxylate Hcl	C	Unknown	2.5 Milligram, Qd	Not Reported
Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown	1200 Milligram, Bid	Not Reported
Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown	Unk, Qd	Not Reported
Epa Dha 720	C	Unknown		Not Reported
Ergocalciferol	C	Unknown	400 International Unit, Qd	Not Reported
Esomeprazole	C	Unknown	40 Milligram, Bid	Not Reported
Esomeprazole	C	Unknown	400 Milligram, Bid	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Milligram, 2 Every 1 Day	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 International Unit, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Ferrous Fumarate	C	Unknown		Not Reported
Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported
Fish Oil	C	Unknown	1200 Milligram, Bid	Not Reported
Folic Acid	C	Unknown		Not Reported
Genteal [Hypromellose]	C	Ophthalmic	Unk	Not Reported
Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown		Not Reported
Loperamide	C	Unknown	2.5 Milligram	Not Reported

Nasonex	C	Unknown	2 Dosage Form, Bid	Not Reported
Nexium [Esomeprazole Magnesium]	C	Unknown	40 Mg, Bid	Not Reported
Vitamin B3	C	Unknown		Not Reported
Omega-3 Fatty Acids	C	Unknown	1200 Mg, Bid	Not Reported
Oxycodone And Acetaminophen	C	Unknown		Not Reported
Oxycodone Terephthalate	C	Unknown		Not Reported
Pantoprazole	C	Unknown	40 Milligram, Qd	Not Reported
Pantoprazole	C	Unknown	400 Milligram, Qd	Not Reported
Perfenazine	C	Oral	10 Milligram	Not Reported
Prednisone	C	Unknown	5 Mg, Qd	Not Reported
Prednisone	C	Unknown	5 Milligram, Q2h	Not Reported
Pyridoxine	C	Unknown		Not Reported
Retinol Palmitate	C	Unknown		Not Reported
Riboflavin	C	Unknown		Not Reported
Thiamine Hcl	C	Unknown		Not Reported
Thiamine Mononitrate	C	Unknown		Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Cyclical	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Qh	Not Reported
Sodium	C	Unknown		Not Reported
Sodium Ascorbate	C	Unknown		Not Reported
Tylenol	C	Oral	1000 Mg, Qd	Not Reported
Vitamin D3	C	Unknown		Not Reported
Vitamin A [Retinol]	C	Unknown		Not Reported
Vitamin B12 [Cyanocobalamin]	C	Unknown		Not Reported
Vitamin D [Ergocalciferol]	C	Unknown	400 Dosage Form, Qd	Not Reported
Xeljanz	C	Oral	5 Milligram, Qd	Not Reported
Fergon	C	Unknown	300 Milligram, Qd	Not Reported
Risedronate Sodium	C	Unknown	36 Milligram, Qwk	Not Reported
Multivitamin [Ascorbic	C	Unknown		Not Reported

Acid;Biotin;Calcium Pantothenate;Cyanocobalamin					
Omega 3 2100		C	Unknown	1200 Milligram, Bid	Not Reported
Percocet [Oxycodone Hydrochloride;Oxycodone Terephthalate;Paracetamol]		C	Unknown	1 Dosage Form, As Required	Not Reported
Pyridoxine Hydrochloride		C	Unknown		Not Reported
Tecta		C	Unknown	40 Milligram, Qd	Not Reported
Vitamin B1 [Thiamine]		C	Unknown		Not Reported
Vitamin C [Ascorbic Acid]		C	Unknown		Not Reported
Acetaminophen		C	Oral	1000 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	13903125	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2017AP016854		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Pain; Rheumatoid Arthritis; Sciatica; Treatment Failure	Apo-Hydroxyquine			S	Oral	400 Mg, Qd		Apotex
	Ramipril			S	Unknown	1 Df, Qd		Apotex
	Ramipril			S	Unknown	Unk Every One Day		Apotex
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	7 Mg, Qd		Not Reported
	Prednisone			S	Unknown	7 Mg, Unk Every One Day		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Acetaminophen			S	Unknown	Unk		Apotex
	Dorzolamide ,Timolol			S	Ophthalmic	Unk		Apotex
	Dorzolamide ,Timolol			S	Unknown	Unk, Bid		Apotex
	Dorzolamide ,Timolol			S	Ophthalmic	Unk, Bid		Apotex
	Dorzolamide ,Timolol			S	Ophthalmic	Unk		Apotex
	Dorzolamide ,Timolol			S	Ophthalmic	2 Df, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported

Actemra	S	Intravenous (not otherwise specified)	600 Mg, 1 Every 4 Weeks	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Levothyroxine	S	Unknown	Unk Unk, Qd	Not Reported
Levothyroxine	S	Unknown	Unk Every One Day	Not Reported
Levothyroxine	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Cosopt	S	Unknown	Unk, Bid	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk, Qd	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Tylenol /00020001/	S	Unknown	Unk	Not Reported
Codeine	S	Unknown	Unk	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Acetaminophen With Codeine	C	Unknown	Unk As Required	Not Reported
Acetaminophen, Caffeine And Dihydrocodeine Bi	C	Unknown		Not Reported
Dorzolamide Hydrochloride W/Timolol Maleate	C	Ophthalmic	Unk, Bid	Not Reported
Plaquenil /00072602/	C	Unknown	400 Mg, Qd	Not Reported
Diphenhydramine	C	Unknown	Unk	Not Reported
Methylprednisolone	C	Unknown	Unk	Not Reported
Methotrexate	C	Subcutaneous	25 Mg, Q.Wk.	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Acetaminophen W/Caffeine	C	Unknown	Unk	Not Reported
Tylenol /00020001/	C	Unknown	Unk	Not Reported

	Caffeine		C	Unknown	Unk	Not Reported
	Hydroxychloroquine Phosphate		C	Unknown	Unk	Not Reported
	Tylenol With Codein /00116401/		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	15855790	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633737-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Drug Ineffective; Infection; Liver Function Test Increased; Musculoskeletal Pain;	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Neck Pain; Pain In Extremity; Seizure; Therapeutic Product Effect Decreased; Thyroid Disorder	Sulfasalazine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition	Anakinra			S	Unknown			Not Reported

Aggravated; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Arava	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Naprosyn [Naproxen]	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Vioxx	S	Unknown	Not Reported
	Xeljanz	C		Not Reported
	Leflunomide	C		Not Reported

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

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

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

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

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

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

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

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

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

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

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

	Methotrexate	S	Unknown	25 Mg, Monthly (Q4w)	Not Reported
	Sulfasalazine	S	Oral	1 G, Bid	Not Reported
	Sulfasalazine	S	Oral	1 G	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S		25 Mg, Weekly	Not Reported
	Xeljanz	C		Unk	Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Disability; Drug Ineffective; Hepatic Enzyme Increased; Ileostomy; Intestinal Obstruction; Musculoskeletal Stiffness;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

Rheumatoid Arthritis; Systemic Lupus Erythematosus; Wheelchair User	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Hydroxychloroquine		S	Oral	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Arava		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Prednisone		C		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Pneumonia	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Intra-arterial			Barr
	Naproxen Sodium			S	Unknown			Teva
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported

	Cimzia	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Kineret	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Arthralgia; Depression;	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer

Drug Ineffective; Frequent Bowel Movements; Gastric Disorder; Glaucoma; Joint Swelling; Musculoskeletal Stiffness; Nausea; Psoriasis	Methotrexate Sodium	S	Subcutaneous	15 Mg, Weekly		Pfizer
	Methotrexate Sodium	S	Subcutaneous	15 Mg, Weekly		Pfizer
	Folic Acid	S	Unknown			Not Reported
	Humira	S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Humira	S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Mg, Unk		Not Reported
	Prednisone	S	Unknown	25 Mg, 1x/Day		Not Reported

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

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

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

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

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

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

Glaucoma; Nausea; Treatment Failure	Methotrexate Sodium	S	Oral	15 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Subcutaneous	15 Mg, Weekly	Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Mg, 1x/Day	Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass; Mass Excision; Nodule; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Subcutaneous	Unk		Not Reported
	Risedronate			S	Unknown	Unk		Apotex
	Risedronate			S	Oral	35 Mg, Q.Wk.		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	22.5 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

	Novo-Rythro	S	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	200 Mg, Bid	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	4000 Iu, Qd	Not Reported
	Marijuana	C	Unknown	Unk	Not Reported
	Risedronate	C	Oral	35 Mg, Q.Wk.	Not Reported
	Wellbutrin	C	Unknown	Unk	Not Reported
	Wellbutrin	C	Unknown	300 Mg, Qd	Not Reported
	Bupropion	C	Unknown	300 Mg, Qd	Not Reported
	Cannabis Sativa	C	Unknown	Unk, Unknown	Not Reported
	Hydroxychloroquine	C	Oral	400 Mg, Qd	Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Adrenal Suppression; Blood Prolactin Increased; Cushing'S Syndrome; Drug Interaction; Galactorrhoea; Hyperprolactinaemia; Myopathy; Orthostatic Hypotension	Itraconazole			S	Oral	100 Mg, Qd		Novartis
	Itraconazole			S	Oral	100 Mg, Qd		Novartis
	Levothyroxine			S	Unknown	75 Mg, Qd		Not Reported
	Domperidone Maleate			S	Unknown	10 Mg, Tid		Not Reported
	Prednisolone Acetate			S	Unknown	7.5 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Immunoglobulin I.V			S	Unknown	Unk		Not Reported
	Creon			S	Unknown	10 Mg, Tid		Not Reported
	Lansoprazole			S	Unknown	30 Mg, Qd		Not Reported
	Uniphyllin			S	Unknown	200 Mg, Bid		Not Reported
	Carbocisteine			S	Unknown	2 Df, Qd		Not Reported
	Carbocisteine			S	Unknown	750 Mg, Bid		Not Reported

	Risedronate	S	Unknown	35 Mg		Not Reported
	Amylase	S	Unknown	10 Mg, Tid		Not Reported
	Propanolol	C	Unknown	Unk		Not Reported

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	15619748	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555750-00		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	15735711	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2595527-00			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	15849613	EXPEDITED (15-DAY)		OT	CA-SA-2019SA012286			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated;	Hydroxychloroquine Sulfate			S				Sanofi
Contraindicated Product Administered; Drug	Hydroxychloroquine Sulfate			S		Unk		Sanofi

Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Hydroxychloroquine Sulfate	S		200 Mg	Sanofi
	Methotrexate	S		15 Mg	Not Reported
	Plaquenil	S	Oral	200 Mg, Bid	Sanofi
	Leflunomide	S		Unk Unk, Qd	Sanofi
	Leflunomide	S		10 Mg, Qd	Sanofi
	Actemra	S			Not Reported
	Humira	S		40 Mg	Not Reported
	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S		Unk	Not Reported
	Prednisone	C			Not Reported
	Arava	C			Not Reported
	Simponi	C			Not Reported
	Xeljanz	C			Not Reported

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

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

	Celebrex	C	Oral	Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Q.H.		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Unk, Cyclical		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Risedronate			S	Oral	35 Mg, Q.Wk.		Doc Generici
	Risedronate			S	Unknown	35 Mg, Q.Wk.		Doc Generici
	Risedronate			S	Unknown	35 Mg, Q.Wk.		Apotex
	Risedronate			S	Oral	35 Mg, Q.Wk.		Apotex
	Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Qid		Apotex
	Hydroxychloroquine			S	Unknown	Unk Unk, Qd		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Q.H.		Apotex
	Hydroxychloroquine			S	Unknown	Unk Unk, Q.Wk.		Apotex
	Hydroxychloroquine			S	Oral	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Unk, Cyclical		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Intravenous (not otherwise specified)	8 Df, Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Rituximab			S	Unknown			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported

	Etanercept	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Medroxyprogesterone Acetate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Anakinra	C		Not Reported
	Cyclosporine	C	Unknown	Not Reported
	Depo-Provera	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Skin Reaction;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

Skin Swelling	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported

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

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

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

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

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

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

Methotrexate	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Atorvastatin	C	Unknown	Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown	Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis;	Methotrexate (Trade Name			S	Other			Not Reported

Therapeutic Product Effect Decreased	Unknown)				
	Humira		S	Subcutaneous	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Simponi		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17491790	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201709-005553			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Pulmonary Toxicity; Visual Impairment	Hydroxychloroquine			S	Oral	Unk		Concordia
	Methotrexate			C		Unk		Not Reported
	Enbrel			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Orencia			C		Unk		Not Reported
	Cimzia			C		Unk		Not Reported
	Simponi			C		Unk		Not Reported
	Inflectra			C		Unk		Not Reported

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Acinetobacter Infection; Brain Abscess; Death; Nocardiosis; Septic Shock; Shunt Infection	Hydroxychloroquine Sulfate		S	Unknown	Appco Pharma
	Prednisolone		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome;	Celecoxib			S	Oral	400 Milligram Daily;		Teva
	Actemra			S	Unknown			Not Reported

Musculoskeletal Stiffness; Pain	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst;	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form- Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Depo-Medrol			C	Intra-articular	Dosage Form- Suspension Intra-Articular		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

Tenosynovitis; Therapeutic Product Effect Decreased; Upper Respiratory Tract Infection; White Blood Cell Count Decreased

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Drug Ineffective; Eye Disorder; Hepatic Enzyme Increased; Musculoskeletal Stiffness; Off Label Use; Pain In Extremity; Peripheral Swelling; Pruritus; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral	20 Mg, Qwk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral			Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	14310480	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050909		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Ankle Fracture; Contraindicated Product Administered; Decreased Appetite; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Swelling;	Cimzia			S	Subcutaneous	Solution		Not Reported
	Actemra			S		162 Milligram		Not Reported
	Arava			S		20 Mg, Once Daily (Qd)		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S		20 Milligram, Once Daily		Not Reported

Malaise; Nausea; Off Label Use; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Unevaluable Event; Vomiting					(Qd)	
	Methotrexate		S		25 Milligram, Weekly (Qw)	Not Reported
	Methotrexate		S	Oral	Unk	Not Reported
	Methotrexate		S	Oral	20 Milligram, Weekly (Qw)	Not Reported
	Methotrexate		S	Subcutaneous	Unk	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Sulfasalazine		S	Oral	2 G, Once Daily (Qd)	Not Reported
	Gold		C			Not Reported
	Plaquenil		C		Unk	Not Reported
	Acetaminophen;Codeine Phosphate		C			Not Reported
	Folic Acid		C			Not Reported
	Hydroxychloroquine		S		400 Milligram	Not Reported
	Prednisone		C		15 Milligram, Once Daily (Qd)	Not Reported
	Pregabalin		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	14956006	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-SAMSUNG BIOEPIS-SB-2017-04909		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased;	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported

Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Drug Specific Antibody Present; Gastroenteritis Viral; Human Anti-Human Antibody Test; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Product Use Issue; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Unknown	Unknown	Not Reported
	Infliximab	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Unknown	Not Reported
	Adalimumab	S	Unknown	Unknown	Not Reported
	Adalimumab	S			Not Reported
	Abatacept	S	Intravenous drip		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous	Unknown	Not Reported

Anakinra	S	Unknown	Unknown	Not Reported
Apo-Hydroxyquine	S	Oral	Unknown	Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown	Unknown	Not Reported
Methotrexate	S	Unknown	Unknown	Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous	Unknown	Not Reported
Methotrexate	S	Unknown	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Unknown	Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Apo-Naproxen	S	Unknown	Unknown	Not Reported
Apo-Naproxen	S	Oral	Tablet (Enteric Coated)	Not Reported
Apo-Naproxen	S	Oral	Tablet (Enteric Coated)	Not Reported
Apo-Naproxen	S	Unknown	Unknown	Not Reported
Apo-Naproxen	S	Oral		Not Reported
Apo-Naproxen	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Triamcinolone Aq	S	Unknown	Unknown	Not Reported
Apo-Triamcinolone Aq	S	Unknown	Spray Metered Dose	Not Reported
Apo-Sulfasalazine	S	Oral		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Tocilizumab	S	Intravenous (not		Not Reported

		otherwise specified)		
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Naproxen	S	Unknown	Unknown	Not Reported
Naproxen	S			Not Reported
Orencia	S	Intravenous drip		Not Reported
Orencia	S	Unknown	Inhalation	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous drip		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Unknown	Unknown	Not Reported
Prednisone	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S			Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unknown	Not Reported
Triamcinolone Acetonide	S	Unknown	Unknown	Not Reported
Triamcinolone Acetonide	S	Unknown	Unknown	Not Reported

Triamcinolone Acetonide	S	Intra-articular	Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Unknown	Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous	Unknown	Not Reported
Humira	S	Subcutaneous	Unknown	Not Reported
Humira	S	Subcutaneous	Unknown. Solution	Not Reported
Humira	S	Unknown	Unknown	Not Reported
Gammagard Liquid Also Know As Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
Gammagard Liquid Also Know As Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
Gammagard Liquid Also Know As Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
Gammagard Liquid Also Know As Immune Globulin (Human)	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Kineret	S	Subcutaneous	Per Syringe Single-Use, Preservative-Free Pre-	Not Reported

				Filled Syringes, Solution Subcutaneous	
	Kineret	S			Not Reported
	Triamcinolone	S	Unknown	Unknown	Not Reported
	Triamcinolone	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Unknown	Not Reported
	Triamcinolone Hexacetonide	S			Not Reported
	Folic Acid	C	Unknown	Unknown	Not Reported

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

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

	Tocilizumab	S	Unknown	160 Milligram	Not Reported
	Cimzia	C	Subcutaneous		Not Reported
	Imuran [Azathioprine Sodium]	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	16471647	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-15759		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Flushing; Interstitial Lung Disease; Off Label Use	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Lumigan Rc			C	Ophthalmic	Unknown		Not Reported
	Nexium			C	Unknown	Unknown		Not Reported
	Suphedrine			C	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

Valsartan	C	Unknown	Unknown		Not Reported
Valsartan	C	Unknown	Unknown		Not Reported
Wellbutrin Xl	C	Unknown	Extended Release		Not Reported
Wellbutrin Xl	C	Unknown			Not Reported
Esomeprazole Sodium	C	Unknown	Unknown		Not Reported
Acetaminophen	C	Unknown			Not Reported
Acetaminophen	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17388691	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2017AP006368		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Back Pain; Constipation; Dactylitis; Diarrhoea; Disability; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Finger Deformity; Inappropriate Schedule Of Product Administration; Inappropriate Schedule Of Product Administration; Inflammation; Injury; Insomnia; Joint Effusion; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Migraine; Muscle Spasms; Nausea; Osteoarthritis; Paraesthesia; Psoriasis; Sleep Apnoea Syndrome; Synovial Cyst; Synovitis; Therapeutic Product Effect	Amitriptyline			S	Unknown	Unk, Unknown		Apotex
	Allopurinol			S	Unknown	Unk		Apotex
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Cymbalta			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Allopurinol			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk, Unknown		Not Reported
	Clonazepam			C	Unknown	1 Mg, Unk		Not Reported
	Ergocalciferol			C	Unknown	4000 Iu, Qd		Not Reported
	Flaxseed Oil			C	Unknown	Unk		Not Reported
	Tylenol /00020001/			C	Unknown	Unk		Not Reported
	D-Alpha Tocopherol			C	Unknown	Unk, Unknown		Not Reported
	Linum Usitatissimum			C	Unknown	Unk		Not Reported

Incomplete; Therapeutic Product Effect Incomplete

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug	Hydroxychloroquine			S	Oral	Unk		Concordia

Ineffective; Drug Ineffective; Drug Ineffective; Dyspepsia; Food Intolerance; Hepatotoxicity; Rash; Rheumatoid Arthritis	Leflunomide	S	Oral	Unk		Not Reported
	Humira	C	Subcutaneous	Unk		Not Reported
	Enbrel	C	Unknown	Unk		Not Reported
	Orencia	C	Unknown	Unk		Not Reported
	Sulfasalazine	C	Unknown	Unk		Not Reported
	Azathioprine	C	Unknown	50 Die		Not Reported
	Azathioprine	C		Unk		Not Reported
	Imuran	C		Unk		Not Reported
	Methotrexate	C		Unk		Not Reported

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

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

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

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

	Mycophenolate Mofetil	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Hypersensitivity; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Soft	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Weekly, (Qow)		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Weekly (Q4w)		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Monthly, Powder And Solution For Solution For Injection	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Myocrisin	S	Unknown	Unk	Not Reported
	Arava	C		20 Mg, Qd	Not Reported
	Arava	C		Unk	Not Reported
	Ativan	C			Not Reported
	Dilaudid	C			Not Reported
	Enablex	C			Not Reported
	Lasix	C			Not Reported
	Loperamide	C			Not Reported
	Norflex	C			Not Reported
	Omnaris	C			Not Reported
	Pantoloc	C			Not Reported
	Synthroid	C			Not Reported
	Vagifem	C			Not Reported
	Abatacept	C			Not Reported
	Rituxan	C			Not Reported
	Kineret	C			Not Reported
	Benadryl Allergy	C			Not Reported
	Cortisone	C			Not Reported
	Desoximetasone	C			Not Reported
	Diphenhydramine	C			Not Reported
	Plantago Ovata	C			Not Reported
	Actemra	C			Not Reported
	Sodium Aurothiomalate	C			Not Reported
	Xeljanz	C			Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Haemorrhage	Hydroxychloroquine			S	Unknown	Unk		Concordia

Erelzi	C	Unk	Not Reported
Methotrexate	C	Unk	Not Reported
Leflunomide	C	Unk	Not Reported
Sulfasalazine	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17500067	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-01			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Arthritis; Rheumatoid Nodule;	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Dosage Form: Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Depo-Medrol			C	Unknown	Suspension Intra-Articular		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Humira			C	Unknown	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

Synovial Cyst;
Tenosynovitis; Upper
Respiratory Tract Infection

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed	Ibuprofen			S	Oral	Unk, (Tablets)		Strides

Suicide; Crying; Dyspnoea; Hypotension; Oxygen Saturation Decreased; Pulmonary Oedema; Pupil Fixed; Salivary Hypersecretion	Naproxen	S	Oral	Unk, (Tablets)	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported

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

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

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

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

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

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

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

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

	Bacillus Calmetteguerin Bcg	C	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	C	Unknown	Not Reported

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	15067533	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015880			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Leflunomide			S	Unknown	Unk		Apotex
	Rituximab			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Bifidobacterium Bifidum			C	Unknown	Unk		Not Reported

Loperamide	C	Oral	Unk		Not Reported
Pantoprazole	C	Unknown	Unk, Tid		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	15076376	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015960		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Herpes Zoster; Rheumatoid Arthritis	Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Etanercept			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	20 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Citalopram			C	Unknown	20 Mg, Qd		Not Reported
	Folic Acid			C	Unknown	5 Mg, Qd		Not Reported
	Losec /00661201/			C	Unknown	20 Mg, Qd		Not Reported
	Naprosyn /00256201/			C	Unknown	500 Mg, Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

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

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

Methotrexate	S	Subcutaneous		Not Reported
Adalimumab	S	Subcutaneous	40 Milligram	Not Reported
Apo-Leflunomide	S			Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	40 Milligram	Not Reported
Hydroxychloroquine Sulfate	S		Unk	Not Reported
Kevzara	S			Not Reported
Leflunomide	S			Not Reported
Methotrexate	S		20 Milligram	Not Reported
Methotrexate	S		10 Milligram	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Tocilizumab	S			Not Reported
Tofacitinib	S			Not Reported
Prednisone	C		10 Milligram	Not Reported
Sulfasalazine	S			Not Reported
Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
Rabeprazole Sodium	C	Oral	20 Milligram, Once Daily (Qd)	Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	160 Milligram, Qwk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Mobicox			S	Unknown	Unk		Not Reported
	Depo-Medrol			C	Intra-articular	80 Milligram, Qd		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			C	Unknown	Unk		Not Reported
	Plaquenil S			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Prednisone			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported

Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Movement Disorder; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomadesis; Onychomycosis	Hydroxychloroquine	S	Oral	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
	Methotrexate	S	Oral	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Plaquenil	S	Oral	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
	Rituximab	S	Subcutaneous	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Simponi	S	Subcutaneous	Unknown	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown	Unknown	Not Reported
	Arava	C	Unknown	Unknown	Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug	Cimzia			S	Subcutaneous	Solution		Not Reported
	Alendronate Sodium			S		70 Milligram, 4x/Week		Not Reported
	Apo-Ibuprofen			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Apremilast			S		60 Milligram, 2x/Day (Bid)		Not Reported
	Apremilast			S		Unk		Not Reported
	Apremilast			S				Not Reported
	Ciclosporin			S		Unk		Not Reported
	Ciclosporin			S		Unk		Not Reported

Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Codeine	S		Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S			Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous	40 Milligram, Solution	Not Reported
	Humira	S			Not Reported
	Humira	S			Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Ibuprofen	S	Oral	600 Milligram	Not Reported
	Infliximab	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S		70 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	S		12 Milligram, 4x/Week	Not Reported
	Methotrexate	S		17.5 Milligram, 4x/Week	Not Reported
	Methotrexate	S		10 Milligram, 4x/Week	Not Reported
	Methotrexate	S		15 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	S		12.5 Milligram, 4x/Week	Not Reported
	Motrin [Ibuprofen]	S	Oral	Unk Unk, Once Daily (Qd)	Not Reported
	Motrin [Ibuprofen]	S	Oral	600 Milligram, Once Daily (Qd)	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S			Not Reported
	Orencia	S		Unk	Not Reported
	Orencia	S			Not Reported
	Otezla	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, 2x/Day (Bid)	Not Reported
	Simponi	S	Subcutaneous	Solution	Not Reported
	Stelara	S	Subcutaneous	Solution	Not Reported

Sulfasalazine	S	Endocervical	Unk		Not Reported
Tocilizumab	S		360 Milligram		Not Reported
Tocilizumab	S		680 Milligram		Not Reported
Enbrel	S		25 Milligram, 2x/Week		Not Reported
Enbrel	S		Unk		Not Reported
Enbrel	S				Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C				Not Reported
Colchicine	C		Unk		Not Reported
Dexilant	C				Not Reported
Febuxostat	C				Not Reported
Folic Acid	C				Not Reported
Gravol	C		Unk		Not Reported
Mogadon	C				Not Reported
Nitrazepam	C				Not Reported
Oxycodone	C				Not Reported
Prednisone	C		Unk		Not Reported
Uloric	C				Not Reported
Xeljanz	C				Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dyspepsia; Eczema;	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

Nodule; Psoriatic Arthropathy; Weight Decreased	Otezla		S	Oral	60 Mg, Bid	Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Meloxicam			S	Unknown	15 Mg, Unk		Apotex
	Humira			S	Subcutaneous	Unk		Not Reported
	Atorvastatin Calcium			C	Unknown	20 Mg, Unk		Not Reported
	Budesonide W/Formoterol Fumarate			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	100 Mg, Unk		Not Reported
	Lansoprazole			C	Unknown	30 Mg, Unk		Not Reported
	Plaquenil /00072602/			C	Unknown	Unk		Not Reported
	Plaquenil /00072602/			C	Unknown	Unk		Not Reported

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

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

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

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

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

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

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

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

Syndrome

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Response	Etanercept			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronic Acid			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Codeine			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unknown		Not Reported
	Leflunomide			S	Oral	Unknown		Not Reported

Decreased; Ulcer	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Myochrysine	S	Parenteral		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Intravenous (not	Unknown	Not Reported

			otherwise specified)		
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Prednisolone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported

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

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

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

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

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

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

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

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

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

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

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

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

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

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

	Hydroxychloroquine Sulfate			S	Unknown					Not Reported
	Leflunomide			S	Unknown					Not Reported
	Methotrexate			S	Unknown					Not Reported
	Remicade			S	Intravenous (not otherwise specified)					Not Reported
	Remicade			S	Intravenous (not otherwise specified)					Not Reported
	Sulfasalazine			S	Unknown					Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown					Not Reported
	Desoximetasone			C	Unknown					Not Reported

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

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

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

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

Contraindicated Product Administered; Dysphonia; Dyspnoea; Odynophagia; Product Use In Unapproved Indication; Rheumatoid Arthritis; Stridor	Rituximab		S	Unknown	Not Reported
	Golimumab		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Condition Aggravated; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Rituxan			S	Intravenous drip	Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Thrombotic Stroke;	Atorvastatin			S	Unknown	Unk		Not Reported

Transient Ischaemic Attack	Clopidogrel		S	Unknown	Unk		Aurobindo
	Rivaroxaban		S	Unknown	Unk		Not Reported
	Apixaban		S	Unknown	Unk		Not Reported
	Hydroxychloroquine		S	Unknown	Unk		Not Reported
	Warfarin		S	Unknown	Unk		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	15841668	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018134129		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Off	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Celebrex			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	10 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	10 Milligram		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	10 Milligram, Qwk		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	50 Milligram, Bid		Not Reported

Label Use; Product Use Issue; Rash; Therapeutic Product Effect Decreased	Clindamycin Hcl	S	Unknown	Unk	Not Reported
	Lopressor	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Biaxin	S	Unknown	Unk	Not Reported
	Keflex [Cefalexin]	S	Unknown	Unk	Not Reported
	Cephalexin [Cefalexin]	S	Unknown	Unk	Not Reported
	Enalapril	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Hctz	S	Unknown	Unk	Not Reported
	Hydralazine Hydrochloride	S	Unknown	Unk	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Losartan	S	Unknown	Unk	Not Reported
	Metoprolol Tartrate	S	Unknown	Unk	Not Reported
	Moxifloxacin Hydrochloride	S	Unknown	Unk	Not Reported
	Pariet	S	Unknown	Unk	Not Reported
	Enalapril Maleate	S	Unknown	Unk	Not Reported
	Hydrochlorothiazide	S	Unknown	Unk	Not Reported
	Losartan Potassium	S	Unknown	Unk	Not Reported
	Isoniazid	S	Unknown	Unk	Not Reported
	Cephalexin Monohydrate	S	Unknown	Unk	Not Reported
	Penicillin G [Benzylpenicillin Sodium]	S	Unknown	Unk	Not Reported
	Penicillin G 2-Amino-4-Methoxy-6-Methylpyrim.	S	Unknown	Unk	Not Reported
	Plaquenil S	S	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Atenolol	C		Unk	Not Reported
	Colchicine	C		Unk	Not Reported
	Coversyl [Perindopril Erbumine]	C		Unk	Not Reported

	Leucovorin [Folinic Acid]	C		Unk	Not Reported
	Levothyroxine Sodium	C		Unk	Not Reported
	Ranitidine	C		Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Hydroxychloroquine	C	Unknown	Unk	Not Reported
	Iron Sucrose	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	8.5 Milligram, Qd	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	16242893	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1269		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic Enzyme Increased; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enalapril Maleate			S	Unknown			Not Reported
	Pantoprazole Magnesium			S	Unknown			Not Reported
	Hydrochlorothiazide			S	Unknown			Not Reported
	Losartan Potassium			S	Unknown			Not Reported
	Isoniazid			S	Unknown			Not Reported

Cephalexin Monohydrate	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Lopressor	S	Unknown	Not Reported
Penicillin G	S	Unknown	Not Reported
Penicillin G (2-Amino-4-Methoxy-6-Methylpyrim)	S	Unknown	Not Reported
Plaquenil S	S	Unknown	Not Reported
Celebrex	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Biaxin	S	Unknown	Not Reported
Cephalexin	S	Unknown	Not Reported
Clindamycin Hydrochloride	S	Unknown	Not Reported
Esomeprazole	C	Unknown	Not Reported
Colchicine	C	Unknown	Not Reported
Coversyl	C	Unknown	Not Reported
Leucovorin	C	Unknown	Not Reported
Levothyroxine Sodium	C	Unknown	Not Reported
Ranitidine	C	Unknown	Not Reported
Atenolol	C	Unknown	Not Reported
Gold	C	Unknown	Not Reported
Hydroxychloroquine	C	Unknown	Not Reported
Iron Sucrose	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction; Maternal	Human Normal Immunoglobulin			S	Transplacental	Unk		Shire
	Human Normal Immunoglobulin			S				Shire

Exposure During Pregnancy; Oligohydramnios; Premature Baby	Hydrocortisone	S	Transplacental	Unk	Not Reported
	Hydrocortisone	S			Not Reported
	Vitamin K Nos	S	Transplacental	Unk	Not Reported
	Vitamin K Nos	S			Not Reported
	Bisulepin	S	Transplacental	Unk	Not Reported
	Bisulepin	S			Not Reported
	Nadroparine	S	Transplacental	Unk	Not Reported
	Nadroparine	S			Not Reported
	Etamsylate	S	Transplacental	Unk	Not Reported
	Privigen	S	Transplacental	Unk	Not Reported
	Privigen	S	Transplacental	Unk	Not Reported
	Privigen	S	Transplacental		Not Reported
	Flebogamma Dif [Immunoglobulin Human Normal]	S	Transplacental	Unk	Not Reported
	Flebogamma Dif [Immunoglobulin Human Normal]	S			Not Reported
	Dexamethasone	S	Transplacental	Unk	Not Reported
	Dexamethasone	S	Transplacental	Unk	Not Reported
	Metoprolol Tartrate	S	Transplacental	Unk	Not Reported
	Metoprolol Tartrate	S			Not Reported
	Potassium Chloride	S	Transplacental	Unk	Not Reported
	Potassium Chloride	S			Not Reported
	Prednisone	S	Transplacental	Unk	Not Reported
	Prednisone	S	Transplacental	Unk	Not Reported
	Vitamin B Complex	S	Transplacental	Unk	Not Reported
	Vitamin B Complex	S			Not Reported
	Albumin	S	Transplacental	Unk	Not Reported
	Albumin	S			Not Reported
	Paracetamol	S	Transplacental	Unk	Not Reported
	Paracetamol	S			Not Reported
	Folic Acid	S	Transplacental	Unk	Not Reported
	Folic Acid	S			Not Reported
	Methylprednisolone Sodium Succinate	S	Transplacental	Unk	Not Reported

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nephrolithiasis; Pain; Pain In Extremity; Peripheral	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Swelling; Product Dose Omission; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid	Methotrexate Sodium			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

Arthritis; Systemic Lupus Erythematosus	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use; Synovitis	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Estrogel			C	Unknown	1.8 Percent Daily;		Not Reported
	Furosemide			C	Unknown			Not Reported

Morphine	C	Unknown			Not Reported
Potassium Chloride	C	Unknown	1500 Milligram Daily;		Not Reported
Valsartan	C	Unknown	320 Milligram Daily;		Not Reported
Xalatan	C	Ophthalmic	50 Microgram Daily;		Not Reported
Zingiber Officinale	C	Oral			Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Injection Site Reaction; Meningitis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Atorvastatin			S				Micro Labs
	Apixaban			S				Micro Labs
	Rivaroxaban			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Clopidogrel			S				Not Reported
	Warfarin			S				Not Reported

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

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

Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate		S	Subcutaneous		Barr
	Hydroxychloroquine /00072603/		S	Unknown	400 Milligram Daily;	Not Reported
	Sulfasalazine		S	Unknown	2000 Milligram Daily;	Not Reported
	Orencia		S	Unknown		Not Reported
	Actemra		S	Unknown		Not Reported
	Apo-Prednisone		S	Oral	5 Milligram Daily;	Not Reported
	Arava		S	Unknown	20 Milligram Daily;	Not Reported
	Humira		S	Subcutaneous	2 Milligram Daily;	Not Reported
	Enbrel		S	Subcutaneous		Not Reported

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

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

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

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

	Sulfate] Xeljanz			C						Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fall; Interstitial Lung Disease; Treatment Failure	Stelara			S	Subcutaneous	4.0 Years		Not Reported
	Bromocriptine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Gold			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Mercaptopurine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Pamidronate Disodium			S	Unknown			Not Reported
	Tenoxicam			S	Unknown			Not Reported
	Xeljanz			S	Unknown	2 Every 1 Days		Not Reported

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

202003001361

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

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

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

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

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

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

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

Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine		S	Unk	Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519592	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2020M1024194		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Drug Interaction; Dyspnoea; Feeling Abnormal; Head Discomfort; Near Death Experience; Palpitations; Reading Disorder	Fluoxetine			S		1 Df, Qd		Not Reported
	Plaquenil /00072602/			S		200 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519909	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-07754			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Etanercept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Cetirizine			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Desoximetasone			S	Oral	Unknown,		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Folic Acid			S	Unknown	Unknown		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Orencia	S	Subcutaneous	Unknown	Not Reported
	Prednisone	S	Unknown	Unknown	Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Simponi	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519917	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-07767		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Etanercept			S	Subcutaneous			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Winpred	S	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
	Desoximetasone	C	Unknown	Unknown	Not Reported
	Methotrexate	C	Oral		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	16191539	EXPEDITED (15-DAY)		HO, LT, OT	JP-GLAXOSMITHKLINE-JP2019JPN049251		30 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Aplasia Pure Red Cell; Haemolysis	Belimumab			S	Intravenous drip	400mg, Once In Every Two Weeks		Glaxosmithkline
	Belimumab			S	Intravenous drip	400mg, Once In Every Four Weeks		Glaxosmithkline
	Plaquenil			S	Oral	200mg, 400mg Alternate Day		Not Reported
	Prograf			S	Oral	3 Mg, 1d		Not Reported
	Predonine Tablets			C		14 Mg, 1d		Not Reported
	Predonine Tablets			C		14 Mg, 1d		Not Reported
	Predonine Tablets			C		13 Mg, 1d		Not Reported
	Predonine Tablets			C		12 Mg, 1d		Not Reported
	Predonine Tablets			C		22 Mg, 1d		Not Reported
	Predonine Tablets			C		32 Mg, 1d		Not Reported
	Predonine Tablets			C		45 Mg, 1d		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	16237399	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018386187		47 YR	Female	CAN

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

Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Off Label Use; Product Use Issue; Rash; Therapeutic Product Effect Decreased	Celebrex	S	Unknown	Unk	Pfizer
	Ciprofloxacin	S	Unknown	Unk	Pfizer
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Weekly	Pfizer
	Enbrel	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	10 Milligram, 1/Week	Pfizer
	Methotrexate Sodium	S	Subcutaneous	10 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	10 Milligram, 1/Week	Pfizer
	Pantoprazole	S		Unk	Pfizer
	Xeljanz	S	Oral	50 Mg, Bid	Pfizer
	Clindamycin Hcl	S	Unknown	Unk	Pfizer
	Lopressor	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Biaxin	S	Unknown	Unk	Not Reported
	Keflex [Cefalexin]	S	Unknown	Unk	Not Reported
	Cephalexin [Cefalexin]	S		Unk	Not Reported
	Enalapril	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Hctz	S	Unknown	Unk	Not Reported
	Hydralazine Hydrochloride	S	Unknown	Unk	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Losartan	S	Unknown	Unk	Not Reported
	Metoprolol Tartrate	S		Unk	Not Reported
	Moxifloxacin Hydrochloride	S	Unknown	Unk	Not Reported
	Pariet	S	Unknown	Unk	Not Reported
	Enalapril Maleate	S		Unk	Not Reported
	Hydrochlorothiazide	S	Unknown	Unk	Not Reported

Losartan Potassium	S	Unknown	Unk	Not Reported
Isoniazid	S	Unknown	Unk	Not Reported
Cephalexin Monohydrate	S	Unknown	Unk	Not Reported
Penicillin G [Benzylpenicillin Sodium]	S	Unknown	Unk	Not Reported
Penicillin G 2-Amino-4-Methoxy-6-Methylpyrim.	S	Unknown	Unk	Not Reported
Plaquenil S	S	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	Unk	Not Reported
Atenolol	C		Unk	Not Reported
Colchicine	C		Unk	Not Reported
Coversyl [Perindopril Erbumine]	C		Unk	Not Reported
Leucovorin [Folinic Acid]	C		Unk	Not Reported
Levothyroxine Sodium	C		Unk	Not Reported
Ranitidine	C		Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Unknown	Unk	Not Reported
Iron Sucrose	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	8.5 Milligram, Qd	Not Reported
Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	16438993	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2017-04887			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Contraindicated Product Administered; Drug Ineffective; Encephalitis; Hypoaesthesia; Off Label Use	Etanercept			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported

Hydroxychloroquine	S	Oral			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Oral			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Leflunomide	S	Oral			Not Reported
Methotrexate	S	Unknown			Not Reported
Orencia	S	Unknown	Unknown		Not Reported
Orencia	S				Not Reported
Acetaminophen	C	Unknown	Unknown		Not Reported
Pregabalin	C	Oral			Not Reported

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

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

	Xeljanz	S	Oral	Not Reported
	Cephalexin	C	Unknown	Not Reported

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

	Xeljanz			C	otherwise specified) Unknown	10 Milligram Daily;				Not Reported

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519533	EXPEDITED (15-DAY)		HO, LT, OT	CA-SAMSUNG BIOEPIS-SB-2020-07587			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea;	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Apo-Naproxen			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution, Unknown		Not Reported

Obesity; Prescribed Underdose; Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Humira	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Triamcinolone	S	Intra-articular	Unknown	Not Reported
	Triamcinolone	S	Unknown	Unknown	Not Reported
	Folic Acid	C	Unknown	Unknown	Not Reported

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

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

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

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

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

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

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

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

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

Pregnancy; Rectal Haemorrhage

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

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

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired	Methotrexate			S	Intramuscular			Barr

Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Therapeutic Product Effect Decreased	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Oral	10 Milligram Daily;	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Leflunomide	S	Oral	10 Milligram Daily;	Not Reported
	Acetylsalicylic Acid	C	Unknown		Not Reported
	Asa	C	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Lantus	C	Subcutaneous		Not Reported
	Lozide	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Ramipril	C	Unknown		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Hypoaesthesia; Impaired Work Ability; Injection Site	Etanercept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Unknown,		Not Reported

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17521749	EXPEDITED (15-DAY)		OT	CA-SA-2020SA060110		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain;	Topicort			S	Cutaneous	Unk		Sanofi
	Actemra			S				Not Reported
	Leflunomide			C				Not Reported
	Xeljanz			C				Not Reported
	Arava			S	Oral			Sanofi
	Cimzia			S	Subcutaneous			Not Reported

Pemphigus; Swelling; Systemic Lupus Erythematosus	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S			Not Reported
	Alendronate Sodium	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Qd	Sanofi
	Hydroxychloroquine Sulfate	S	Oral	400 Mg, Qd	Sanofi
	Methotrexate	S	Oral		Not Reported
	Orencia	S			Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Prednisone	S			Not Reported
	Cetirizine Hydrochloride	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2 G, Qd	Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Eye Disorder; Psoriasis; Rash; Rheumatoid Arthritis; Synovitis	Hydroxychloroquine			S				Sanofi
	Methotrexate			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S		Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported

Desvenlafaxine Succinate	C		Not Reported
Prednisone	C		Not Reported
Quetiapine Fumarate	C		Not Reported
Xeljanz	C		Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis;	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported
	Apo-Prednisone			S	Unknown	50 Mg, Unk		Not Reported

Nausea; Neck Deformity; Neck Mass; Off Label Use; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Apo-Prednisone	S	Unknown	25 Mg, 1x/Day	Not Reported
	Apo-Prednisone	S	Oral	3 Mg, 1x/Day	Not Reported
	Arava	S	Unknown	20 Mg, 1x/Day	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Gold Radioactive Colloidal	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, 1x/Day	Not Reported
	Indometacin	S	Unknown	Unk	Not Reported
	Indomethacin	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg, 1x/Day	Not Reported
	Prednisone	S	Oral	3 Mg, 1x/Day	Not Reported
	Prednisone	S	Oral	50 Mg, Weekly	Not Reported
	Prednisone	S	Oral	25 Mg, 1x/Day	Not Reported
	Prednisone	S		50 Mg, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Cymbalta	C	Unknown	30 Mg, 1x/Day	Not Reported
	Folic Acid	C	Oral	Unk Unk, Weekly	Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Failure	Hydroxychloroquine	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Leflunomide	C	Unknown			Not Reported
	Prednisone	C	Unknown	20 Milligram Daily;		Not Reported
	Sulfasalazine	C	Unknown			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Diabetes Mellitus; Flushing; Gastrointestinal Disorder; Headache; Hepatic Steatosis; Herpes Zoster; Hypertension; Liver Function Test Increased; Nervous System Disorder; Off Label Use; Osteoarthritis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Vomiting	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Gadolinium-Zeolite Xanthan Gum Complex			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Escitalopram Oxalate			C	Oral	10 Milligram Daily;		Not Reported
	Humira			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Oral	40 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17526155	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-07599		62 YR	Female	CAN

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

Adverse Event; Ankylosing Spondylitis; Arthropathy; Condition Aggravated; Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Impaired Gastric Emptying; Influenza; Off Label Use; Osteoarthritis; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Infliximab	S	Unknown	Unknown	Not Reported
	Actemra	S	Subcutaneous	Unknown	Not Reported
	Apo-Azathioprine	S	Unknown	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Ciclosporin	S	Unknown	Unknown	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Intramuscular	Unknown	Not Reported
	Humira	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown,	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unknown	Not Reported
	Sulfasalazine	S	Oral	Unknown	Not Reported
	Xeljanz	S	Oral		Not Reported
	Meloxicam	C	Oral		Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alanine Aminotransferase Increased; Alopecia; Anxiety; Arthralgia; Aspartate Aminotransferase Increased; Asthenia; Depression; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis;	Infliximab			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Actemra			S				Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported

Treatment Failure	Orencia	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown		Not Reported
	Rituximab	S	Unknown	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
	Xeljanz	S	Oral		Not Reported
	Gabapentin	C	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Cetirizine Hydrochloride	C	Unknown		Not Reported

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	13855498	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070302		39 YR	Female	CAN

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

Abdominal Discomfort; Arthropathy; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Musculoskeletal Disorder; Off Label Use; Skin Warm	Orencia	S	Unknown	Unk	Bristol Myers Squibb
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	C	Subcutaneous	25 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	14735736	EXPEDITED (15-DAY)		OT	CA-SA-2018SA098039			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Celecoxib			S	Unknown	Unk Unk,Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Bifidobacterium Bifidum			C	Unknown	Align Digestive Aid		Not Reported
	Loperamide			C	Oral	2mg/1-2-Tabs 4x Per Day; Ongoing		Not Reported
	Pantoprazole			C	Unknown	Unk Unk,Tid		Not Reported
	Xeljanz			C	Oral	5 Mg,Bid		Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17485746	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202002001107			Unknown	CAN

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

Drug Ineffective; Encephalitis; Meningitis; Treatment Failure; Unevaluable Event	Hydroxychloroquine	S	Oral	200 Mg, Qd (1 And 1/2 Tablets), Tablet	Concordia
	Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Prednisone	S	Unknown	Unk, On And Off	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Methotrexate	C		Unk	Not Reported
	Sulfasalazine	C		Unk	Not Reported
	Enbrel	C		Unk	Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Product Effect Decreased; Treatment Failure	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Unknown	Not Reported
	Desoximetasone	C	Oral	Not Reported

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

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

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Femur Fracture	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous	200 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Atrovent			C				Not Reported
	Benztropine Mesylate			C				Not Reported
	Chlordiazepoxide			C				Not Reported

	Folic Acid	C	Not Reported
	Levomepromazine Maleate	C	Not Reported
	Methotrexate	C	Not Reported
	Pantoprazole	C	Not Reported
	Risedronate Sodium	C	Not Reported
	Salbutamol	C	Not Reported
	Trifluoperazine [Trifluoperazine Hydrochloride]]	C	Not Reported
	Zopiclone	C	Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Liver Disorder; Renal Disorder	Methotrexate			S	Subcutaneous	25 Mg, 1 Every 1 Week		Barr
	Hydroxychloroquine Sulfate			S	Oral	40 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Oral	Unk		Novartis
	Cyclosporine			S	Unknown	Unk		Novartis
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg (Solution)		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk (Solution)		Not Reported
	Rituxan			S	Unknown	Unk (Solution)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	30 Mg/Kg		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear Of Injection; Musculoskeletal Disorder; Pulmonary Sarcoidosis; Rheumatoid Arthritis	Morphine Sulfate			S	Unknown	Unk		Purdue
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Methotrexate	S	Oral	25 Mg, Weekly		Not Reported
Sulfasalazine	S	Oral	1000 Mg, Bid		Not Reported
Prednisone	C				Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Headache; Tremor	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	9421143	EXPEDITED (15-DAY)		OT	PHHY2013FR077105		57 YR	Female	FRA

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	11457175	NON-EXPEDITED		CA, DS, HO, OT	CA-AMGEN-CANSP2015088317		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased;	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Unk		Not Reported

Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Nail Operation; Onychomadesis; Onychomycosis	Sulfasalazine	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
	Xeljanz	S	Unknown	5 Milligram	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Arava	C	Oral	Unk	Not Reported

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	11962064	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2012074066		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Bone	Enbrel			S	Subcutaneous	Unk		Amgen

Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Enbrel	S			Amgen
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Apo-Leflunomide	S	Oral	5 Milligram, Bid	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Naproxen	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Prednisone Acetate	S	Unknown	Unk	Not Reported
	Aleve	S	Unknown	Unk	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk Unk, Cyclical (1 Every Two Days)	Not Reported
	Leflunomide	S	Unknown	Unk Unk, Bid	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Naproxen Sodium	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Plaquenil	C	Unknown	Unk	Not Reported
	Folic Acid	C	Subcutaneous	Unk	Not Reported
	Hcq	C		Unk	Not Reported
	Acetaminophen And Codeine	C	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	2 Dosage Form, Qd	Not Reported

Insulin	C	Unknown	Unk		Not Reported
Metformin	C	Unknown	2 Dosage Form, Bid		Not Reported
Tylenol	C	Unknown	Unk		Not Reported
Naproxen	C	Unknown	Unk		Not Reported
Methotrexate	C	Unknown	20 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	12133375	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016018438		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Unevaluable Event	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Apo-Azathioprine			S	Unknown	100 Milligram		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Minocycline Hydrochloride			S	Unknown	50 Milligram		Not Reported
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	40 Milligram, Q2wk		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Humira			S	Subcutaneous	400 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	400 Milligram		Not Reported
	Plaquenil			S	Oral	200 Milligram, Bid		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported

Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Xeljanz	S	Unknown	5 Nanogram, Bid	Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
Apo-Minocycline	S	Unknown	50 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk Unk, Qmo	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	500 Milligram, Qd	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Minocycline	S	Unknown	Unk	Not Reported
Minocycline	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	100 Milligram	Not Reported
Arava	S	Oral	20 Milligram, Qwk	Not Reported
Arava	S	Oral	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Methotrexate Sodium	S	Subcutaneous	25 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	20 Unk, Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Amoxil	C	Unknown	Unk	Not Reported

Gold	C	Unknown	Unk		Not Reported
Clavulin	C		Unk		Not Reported
Amoxicillin Trihydrate And Clavulanate Potass	C	Unknown	Unk		Not Reported
Bcg Vaccine	C	Intravenous (not otherwise specified)	Unk		Not Reported
Bcg Vaccine	C	Intravenous (not otherwise specified)	Unk		Not Reported
Bcg Vaccine	C	Unknown	Unk		Not Reported
Adalimumab	C		Unk		Not Reported
Amoxicillin Sodium And Clavulanate Potassium	C	Unknown	Unk		Not Reported
Amoxicillin Sodium And Clavulanate Potassium	C	Unknown	Unk		Not Reported
Risedronate	C	Oral	35 Milligram, Qwk		Not Reported
Amoxicillin	C		Unk		Not Reported
Amoxil [Amoxicillin Trihydrate]	C	Unknown	Unk		Not Reported
Hydroxychloroquine	C	Subcutaneous	400 Milligram		Not Reported
Hydroxychloroquine	C	Unknown	400 Milligram		Not Reported
Hydroxychloroquine	C	Unknown	100 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	12172769	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2016029473		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Bone Hypertrophy; Contraindicated Product	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	488 Mg, Q4wk		Not Reported
	Actemra			S	Oral	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, Qmo		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Qd		Not Reported

Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Q4wk	Not Reported
	Orencia	S	Subcutaneous	Unk, Qwk	Not Reported
	Orencia	S	Vaginal	750 Milligram, Qmo	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Q3wk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Qmo	Not Reported
	Sulfasalazine	S	Oral	2.5 Gram, Qd	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	7.5-12.5 Milligram, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	Unk Unk, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Qwk	Not Reported
	Celebrex	S	Oral	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Q3wk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Gabapentin	S	Oral	100 Milligram, Bid	Not Reported
	Omega-3	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Diphenoxylate	C		2.5/0.25 Milligram, Qd	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Milligram 1-3 Tabs, Qhs	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Milligram	Not Reported
	Omega-3 Fatty Acids	C	Unknown	1200 Mg, Bid	Not Reported
	Vitamin D	C		400 Unit, Qd	Not Reported

Actonel	C		36 Mg, Qwk	Not Reported
Prednisone	C	Unknown	5 Milligram, Qd	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, (Every Four Weeks)	Not Reported
Aclasta	C		750 Milligram, Qmo	Not Reported
Calcium	C		Unk	Not Reported
Genteal	C		3m Use As Directed	Not Reported
Tylenol	C	Oral	500 Mg 2 Tabs, Od	Not Reported
Nexium	C		40 Milligram One Tab, Bid	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Qhs	Not Reported
Nasonex	C		2 Sprays Per Nostrils, Bid	Not Reported
Percocet	C		1 Tab, 4-6h Prn For Pain	Not Reported
Lomotil	C		2.5 Milligram, 3-4 Times/Day	Not Reported
Lomotil	C		2.5 Milligram, Qd	Not Reported
Docosahexaenoic Acid W/Eicosapentae	C	Unknown	Unk Unk, Qd	Not Reported
Docosahexaenoic Acid W/Eicosapentae	C	Unknown	Unk, Q2wk	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Milligram, Bid	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram, Qd	Not Reported
Diphenoxylate Hydrochloride	C		Unk, Qd	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Milligram, Bid	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C		1 Unk	Not Reported
Trazodone	C		Unk	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	40 Milligram, Bid	Not Reported
Loperamide Hydrochloride	C		2.5 Milligram	Not Reported
Ergocalciferol	C		400 International Unit, Qd	Not Reported
Perphenazine	C	Oral	10 Milligram	Not Reported

Tecta	C		40 Milligram, Qd	Not Reported
Vitamin E [Tocopherol]	C		Unk	Not Reported
Fergon	C		300 Milligram, Qd	Not Reported
Ascorbic Acid	C		Unk	Not Reported
Biotin	C		Unk	Not Reported
Cholecalciferol	C		Unk	Not Reported
Ferrous Fumarate	C		Unk	Not Reported
Ferrous Gluconate	C	Unknown	300 Milligram, Qd	Not Reported
Folic Acid	C		Unk	Not Reported
Pantoprazole	C		Unk	Not Reported
Retinol Palmitate	C		Unk	Not Reported
Thiamine Hydrochloride	C		Unk	Not Reported
Riboflavin	C		Unk	Not Reported
Vitamin A [Retinol]	C		Unk	Not Reported
Vitamin B3	C		Unk	Not Reported
Vitamin B1 [Thiamine]	C		Unk	Not Reported
Vitamin B12 [Cyanocobalamin]	C		Unk	Not Reported
Vitamin B6	C		Unk	Not Reported
Vitamin C [Ascorbic Acid]	C			Not Reported
Acetaminophen	C		Unk	Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical Device Implantation	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	200 Milligram, Qmo		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	2000 Milligram, Qmo		Not Reported

	Humira	S	Subcutaneous	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Qd	Not Reported
	Plaquenil	S	Unknown	200 Milligram, Qd	Not Reported
	Folic Acid	S	Unknown	1 Milligram, Qd	Not Reported
	Arava	S	Unknown	20 Milligram, Qd	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	12321534	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2016054557		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disability; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Rash; Skin Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram, Qmo		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qmo		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Bid		Not Reported

Apo-Hydroxyquine	S	Oral	400 Mg, Qd		Not Reported
Methotrexate Sodium	S	Oral	25 Mg, Unk		Not Reported
Cimzia	S	Unknown	Unk		Not Reported
Orencia	S	Subcutaneous	125 Milligram, Qwk		Not Reported
Plaquenil	S	Oral	400 Milligram, Qd		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd		Not Reported
Prednisone Acetate	S	Unknown	Unk		Not Reported
Tofacitinib Citrate	S	Oral	5 Milligram, Bid		Not Reported
Ergocalciferol	C	Unknown	Unk		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alopecia; Arthralgia; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Thyroxine Decreased;	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S				Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

Treatment Failure; Vomiting	Methotrexate	S	Unknown	25 Milligram, Qd	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Otezla	S	Unknown	Unk	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Methadone	S	Unknown	Unk	Not Reported
	Rampril	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Xalatan	C	Ophthalmic	50 Microgram, Qd (50 Mcg 0.005% 1 Drop)	Not Reported
	Cosopt	C		Unk, Bid	Not Reported
	Furosemide	C	Unknown	40 Milligram, Qd	Not Reported
	Valsartan	C	Unknown	320 Milligram, Qd	Not Reported
	Vitamin D	C		10000 Unit, Qwk	Not Reported
	Gravol Ginger	C		500 Milligram, As Needed	Not Reported
	Potassium Chloride	C	Unknown	1500 Milligram, Qd	Not Reported
	Morphine	C	Unknown	Unk Unk, As Necessary	Not Reported
	Dorzolamide Hcl And Timolol Maleate	C	Unknown	Unk Unk, Bid	Not Reported
	Ergocalciferol	C	Unknown	Unk Unk, Qwk	Not Reported
	Ergocalciferol	C	Unknown	Unk, Qd	Not Reported
	Zingiber Officinale	C	Oral	500 Milligram	Not Reported
	Estradiol	C		Unk, Tid	Not Reported
	Estrogel	C		0.6 Percent, Tid	Not Reported
	Estrogel	C	Unknown	1 Dosage Form, Qd	Not Reported

Calcium	C	500 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	12685066	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016109223		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	100 Milligram		Not Reported
	Azathioprine			S	Unknown	100 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Apo Hydroxyquine			S	Unknown	400 Mg, Unk		Not Reported
	Apo-Azathioprine			S	Unknown	100 Milligram		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide	C	Unknown	Unk		Not Reported
	Leflunomide	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	13251335	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006763		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Swelling; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisone			S	Unknown	1.0 Df, Qd		Not Reported
	Pregabalin			S	Oral	Unk		Not Reported
	Piroxicam			S	Unknown	Unk		Not Reported
	Apo-Mycophenolate			S	Unknown	Unk		Novartis
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cellcept /01275102/			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Lyrica			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Intra-arterial	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not	Unk		Not Reported

			otherwise specified)			
	Simponi	S	Subcutaneous	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Plaquenil /00072602/	S	Oral	Unk		Not Reported
	Gold	S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk		Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein	Cosentyx			S	Unknown	Unk		Novartis

Abnormal; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased; Synovitis	Enbrel	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Otezla	S	Oral	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	14921584	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044591			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain;	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Hydroxychloroquine Phosphate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	17.5 Milligram		Not Reported
	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	160 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Therapeutic Product Effect Decreased; Upper Respiratory Tract Infection; White Blood Cell Count Decreased	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Mobicox	S	Unknown	Unk	Not Reported
	Humira	C	Subcutaneous	Unk	Not Reported
	Diclofenac	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Depo-Medrol	C	Intra-articular	80 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Arava			S	Oral	10 Mg, 2 Times/Wk		Not Reported
	Arava			S	Oral	10 Mg, 3 Times/Wk		Not Reported
	Arava			S	Oral	10 Mg, 1 Every 2 Days		Not Reported
	Arava			S	Oral	10 Mg, Qd 3 Months		Not Reported
	Arava			S	Oral	200 Mg, 2 Times/Wk		Not Reported
	Arava			S	Oral	10 Mg, Unk		Not Reported
	Arava			S	Unknown	200 Mg, 2 Times/Wk		Not Reported
	Arava			S	Oral	10 Mg, Q3wk		Not Reported
	Arava			S	Unknown	10 Mg, Qd		Not Reported
	Arava			S	Oral	10 Mg, Bid		Not Reported
	Arava			S	Oral	10 Mg, Q3mo		Not Reported
	Arava			S	Unknown	200 Mg, Unk		Not Reported

Humira	S	Subcutaneous	40 Mg, Cyclical	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Subcutaneous	12.5 Mg, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	12.5 Mg, Qd	Not Reported
Methotrexate Sodium	S	Unknown	Unk 2 Year	Not Reported
Methotrexate Sodium	S	Intramuscular	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Plaquenil	S	Oral	200 Mg, Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Rituxan	S	Unknown	1000 Mg, Cyclical	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Cyclical	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Methotrexate	S	Intramuscular	Unk	Not Reported
Methotrexate	S	Subcutaneous	12.5 Mg, Unk	Not Reported
Methotrexate	S	Unknown	12.5 Mg, Unk	Not Reported
Methotrexate	S	Subcutaneous	40 Mg, Unk	Not Reported
Methotrexate	S	Subcutaneous	12.5 Mg, Qwk	Not Reported
Methotrexate	S	Intramuscular	12.5 Mg, Qd	Not Reported
Methotrexate	S	Unknown	12.5 Mg, Qwk	Not Reported
Methotrexate	S	Unknown	Unk Unk, 1 Every 2 Years	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported

Hydroxychloroquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	15486757	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016023969		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm	Enbrel			S	Unknown	Unk		Amgen
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown	Unk		Not Reported

Malignant; Off Label Use; Onychoclasis; Synovitis; Tooth Loss	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Zostavax	S	Subcutaneous	Unk	Not Reported
	Zostavax	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Zostavax	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous	Unk	Not Reported
	Varicella Zoster Vaccine Live	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Voltaren	C	Unknown	100 Milligram, Qd	Not Reported
	Cortisone	C		10 Milligram, Qd	Not Reported
	Cortisone	C	Oral	Unk	Not Reported
	Cortisone	C	Subcutaneous	Unk	Not Reported
	Desoximetasone	C	Oral	10 Milligram, Qd	Not Reported
	Desoximetasone	C	Unknown	10 Milligram, Qd	Not Reported

Desoximetasone	C	Subcutaneous	Unk		Not Reported
Diclofenac	C	Unknown	100 Milligram, Qd		Not Reported
Diclofenac	C	Unknown	100 Milligram		Not Reported
Diclofenac	C	Subcutaneous	100 Milligram		Not Reported
Cortisone Acetate	C	Subcutaneous	Unk		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Xeljanz	C	Oral	10 Milligram, Bid		Not Reported
Xeljanz	C	Oral	Unk (2 Every 1 Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	16174170	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019151161		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Contraindicated Product Administered; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Pantoprazole			S	Unknown	Unk		Pfizer
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Pfizer
	Celebrex			S	Unknown	Unk		Pfizer
	Ciprofloxacin			S	Unknown	Unk		Pfizer
	Clindamycin Hcl			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	10 Milligram, 1/Week		Pfizer
	Avelox			S	Unknown	Unk		Not Reported
	Keflex [Cefalexin]			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Biaxin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Biaxin			S	Unknown	Unk		Not Reported
	Enalapril Maleate			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Hctz			S	Unknown	Unk		Not Reported
	Hydralazine Hydrochloride			S	Unknown	Unk		Not Reported

Levaquin	S	Unknown	Unk	Not Reported
Losartan Potassium	S	Unknown	Unk	Not Reported
Pariet	S	Unknown	Unk	Not Reported
Penicillin G [Benzylpenicillin]	S	Unknown	Unk	Not Reported
Lopressor	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
Cephalexin Monohydrate	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	S	Unknown	Unk	Not Reported
Cipro [Ciprofloxacin]	S	Unknown	Unk	Not Reported
Cipro [Ciprofloxacin]	S	Unknown	Unk	Not Reported
Penicillin [Benzylpenicillin]	S	Unknown	Unk	Not Reported
Isoniazid	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
Iron Sucrose	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	8.5 Milligram, Qd	Not Reported
Hydroxychloroquine	C		Unk	Not Reported
Hydroxychloroquine Sulfate	C		Unk	Not Reported
Cipro [Ciprofloxacin]	C	Unknown	Unk	Not Reported
Cipro [Ciprofloxacin]	C	Unknown	Unk	Not Reported

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

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

Intolerance; Drug-Induced Liver Injury

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17449223	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007791		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Off Label Use; Oral Discomfort; Treatment Failure; Uveitis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Subcutaneous	40 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Adalimumab			S	Subcutaneous	40 Mg, Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	10 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported

	Orencia	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Tofacitinib	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Kevzara	S	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	10 Mg, Unk	Not Reported
	Rabeprazole Sodium	C	Oral	20 Mg, Qd	Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Back Disorder; Blood Albumin Decreased; C-Reactive Protein Increased; Condition Aggravated; Diverticular Perforation; Diverticulum; Drug Ineffective; Drug Intolerance; Hand Deformity; Headache; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphadenopathy; Musculoskeletal Stiffness;	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous	3.5714 Milligram Daily;		Barr
	Apo-Prednisone			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	7.1429 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naprosyn E			S	Unknown	1000 Milligram Daily;		Not Reported
	Orencia			S	Subcutaneous	17.8571 Milligram Daily;		Not Reported
	Orencia			S	Sunconjunctival			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Methotrexate			S	Subcutaneous			Not Reported

Neck Mass; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Thrombocytosis	Ergocalciferol		C	Unknown		Not Reported
	Folic Acid		C	Unknown		Not Reported
	Gabapentin		C	Unknown		Not Reported
	Lovastatin		C	Unknown		Not Reported
	Metoprolol		C	Unknown		Not Reported
	Naproxen		C	Unknown		Not Reported
	Naproxen Sodium		C	Unknown		Not Reported
	Pantoprazole		C	Unknown		Not Reported
	Rosuvastatin		C	Unknown		Not Reported
	Rosuvastatin Calcium		C	Unknown		Not Reported
	Tramadol Hydrochloride		C	Unknown		Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Uveitis	Cosentyx			S	Unknown	Unk		Novartis
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo Hydroxychloroquine			S	Unknown	400 Mg		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	2 G		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17491286	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008190		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Leflunomide			S	Unknown	Unk, Unknown		Apotex
	Enbrel			S	Unknown	Unk, Unknown		Not Reported
	Methotrexate			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk, Unknown		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Rituxan			S	Unknown	Unk, Unknown		Not Reported
	Rituximab			S	Unknown	Unk, Unknown		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17507283	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008205			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Dermatitis Allergic; Drug Ineffective; Drug Intolerance; Hepatotoxicity; Osteoarthritis; Pneumocystis Jirovecii Pneumonia; Rheumatoid Arthritis; Urticaria	Leflunomide			S	Oral	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported
	Sulfasalazine			S	Unknown	750 Mg, Qd		Not Reported
	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported
	Hydrochlorothiazide W/Lisinopril			C	Unknown	Unk		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dactylitis; Drug Ineffective; Dry Skin; Emphysema;	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hypoaesthesia; Hypoaesthesia; Joint Injury; Joint Swelling; Joint Swelling; Nausea; Paraesthesia; Psoriatic Arthropathy; Rash; Rheumatoid Nodule; Therapeutic Product Effect Incomplete	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral	10mg To 15mg	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Cosentyx	S	Intramuscular		Not Reported
	Cosentyx	S	Oral		Not Reported
	Abatacept	C	Subcutaneous		Not Reported
	Tocilizumab	C	Subcutaneous		Not Reported
	Leflunomide	C			Not Reported
	Leflunomide	C			Not Reported
	Leflunomide	C			Not Reported

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

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

	Azathioprine	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported

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

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

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

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

Immune Reconstitution Inflammatory Syndrome; Whipple'S Disease	Methylprednisolone		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Teva
	Celecoxib		C	Unknown	Not Reported
	Cyclobenzaprine		C	Unknown	Not Reported

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17530896	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201901-000152			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Concordia
	Hydroxychloroquine			S	Oral	200 Mg, Bid, Plaquenil		Concordia
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	Unk Unk, Qd		Not Reported
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	40 Mg, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Enbrel	S	Subcutaneous	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Unknown	Unk		Not Reported
	Prednisone	C		Unk		Not Reported
	Arava	C		Unk		Not Reported
	Simponi	C		Unk		Not Reported
	Xeljanz	C		Unk		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Cytotec			S		Unk		Pfizer
	Prevacid			S		Unk		Not Reported
	Cyclosporine			S		Unk		Not Reported
	Zelnorm			S		Unk		Not Reported
	Amitiza			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Reglan			S		Unk		Not Reported
	Maxzide			S		Unk		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Dizziness; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Celecoxib			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Oral	25 Mg,Qw		Not Reported

Ineffective; Drug Ineffective; Drug Ineffective; Fear Of Injection; Joint Swelling; Loss Of Personal Independence In Daily Activities; Oedema Peripheral; Pain In Extremity; Rheumatoid Arthritis; Stress; Vomiting	Prednisone	S	Oral	5 Mg,Qd	Not Reported
	Sulfasalazine	S	Unknown	Unk Unk,Unk	Not Reported
	Enbrel	S	Unknown	Unk Unk,Unk	Not Reported
	Humira	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Domperidone	C	Oral	10 Mg,Qd	Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Haemolytic Anaemia; Product Use In	Rituximab			S	Unknown	Unk		Not Reported

Unapproved Indication	Rituximab	S				Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk		Novartis
	Mycophenolate Mofetil	S				Novartis
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S				Not Reported
	Tacrolimus	S	Unknown	Unk		Not Reported
	Tacrolimus	S				Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Dilatation; Arthralgia; Drug Ineffective; Joint Swelling; Pulmonary Mass	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, 3x/Day		Pfizer
	Hydroxychloroquine			S		700 Mg, 1x/Day		Not Reported
	Kevzara			S		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Vitamin D [Ergocalciferol]			C		Unk		Not Reported
	Candesartan			C	Unknown	Unk		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported

Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Ilaris Single-Use Vial	S	Unknown	Not Reported
	Ilaris Single-Use Vial	S	Intravenous (not otherwise specified)	Not Reported
	Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
	Ilaris Single-Use Vial	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Drug Ineffective; Drug	Methotrexate			S	Unknown			Barr

Ineffective; Fall; Fear Of Injection; Injection Site Warmth; Skin Reaction; Stress; Weight Increased; Wrist Fracture	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	11368759	NON-EXPEDITED		DE, HO, LT, OT	CA-AMGEN-CANSP2014104837		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Product Use In Unapproved Indication; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis;	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Gold			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Marijuana	S	Unknown	Unk	Not Reported
	Minocycline	S	Unknown	Unk	Not Reported
	Oxycodone	S	Unknown	10 Milligram	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Ilaris	S	Unknown	Unk	Not Reported
	Ilaris	S	Unknown	Unk	Not Reported
	Ilaris	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg, Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk, Solution For Infusion	Not Reported

Xeljanz	S	Oral	Unk Unk, Bid		Not Reported
Xeljanz	S	Unknown	5 Milligram, Q2wk		Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Oxyquinoline Sulfate	S	Unknown			Not Reported
Oxyquinoline Sulfate	S				Not Reported
Kineret	C		Unk		Not Reported
Lyrica	C	Oral	Unk		Not Reported
Rituximab W/Urelumab	C	Unknown	Unk		Not Reported
Prednisone	C		Unk Unk, Qd		Not Reported
Urelumab	C	Unknown	Unk		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Migraine; Neck Pain; Nodule; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	12072431	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016015699		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Apo Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	12164789	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016118471		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug	Enbrel			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	10 Mg, 2x/Day (Bid)		Pfizer

Tolerance Decreased; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Synovitis; Tooth Loss	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Sulfasalazine	S	Unknown	500 Mg, Unk	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Zostavax	S	Subcutaneous	Unk	Not Reported
	Zostavax	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Zostavax	S	Unknown	Unk	Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous	Unk	Not Reported
	Varicella Zoster Vaccine Live	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Voltaren [Diclofenac]	C	Unknown	100 Mg, 1x/Day	Not Reported
	Cortisone	C		10 Mg, Daily	Not Reported

	Desoximetasone	C	Oral	10 Mg, 1x/Day	Not Reported
	Desoximetasone	C		10 Milligram, Qd	Not Reported
	Desoximetasone	C	Oral	5 Mg, 2x/Day	Not Reported
	Desoximetasone	C	Subcutaneous	Unk	Not Reported
	Diclofenac	C	Unknown	100 Mg, 1x/Day	Not Reported
	Diclofenac	C	Oral	100 Mg, Unk	Not Reported
	Diclofenac	C	Oral	5 Mg, 2x/Day	Not Reported
	Diclofenac	C	Unknown	100 Mg, Unk	Not Reported
	Diclofenac	C	Subcutaneous	100 Mg, Unk	Not Reported
	Cortisone Acetate	C	Subcutaneous	Unk	Not Reported
	Cortisone	C	Subcutaneous	Unk	Not Reported
	Cortisone	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	12224346	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015029495		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling;	Enbrel			S	Subcutaneous	25 Milligram, 2 Times/Wk		Amgen
	Enbrel			S	Unknown	25 Milligram, Bid		Amgen
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk		Amgen
	Enbrel			S	Unknown	25 Milligram		Amgen
	Enbrel			S	Unknown	25 Milligram, Q2wk		Amgen
	Enbrel			S	Subcutaneous	25 Milligram		Amgen
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qd		Not Reported
	Methotrexate			S	Vaginal	25 Milligram, 4 Times/Wk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, 4 Times/Wk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Xeljanz	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira	S	Unknown	200 Milligram, Bid	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	200 Milligram, Bid	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Qmo	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	200 Milligram	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Qmo	Not Reported
	Orencia	S	Unknown	Unk Unk, Qd	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	25 Milligram, Qwk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	4.0 Milligram	Not Reported

Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	40 Milligram	Not Reported
Arava	S	Unknown	20 Milligram, Qd	Not Reported
Arava	S	Unknown	20 Milligram	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Benadryl	C	Unknown	Unk Unk, As Necessary	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Unk	Not Reported
Lasix	C		40 Milligram, Tid	Not Reported
Lasix	C	Unknown	Unk	Not Reported
Enablex	C	Unknown	Unk, As Necessary	Not Reported
Enablex	C	Unknown	Unk	Not Reported
Ativan	C	Unknown	1 Gram, Qd At Bedtime	Not Reported
Ativan	C	Unknown	Unk	Not Reported
Ativan	C	Unknown	1 Gram	Not Reported
Loperamide	C	Unknown	2 Milligram, Bid	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown	Unk Unk, Bid	Not Reported
Omnaris	C	Unknown	Unk	Not Reported
Pantoloc	C	Unknown	Unk	Not Reported
Vagifem	C	Vaginal	Unk	Not Reported
Vagifem	C	Unknown	Unk	Not Reported
Cortisone	C	Intra-arterial	Unk	Not Reported
Dilaudid	C	Unknown	4 Milligram, Qd	Not Reported

Dilaudid	C	Unknown	4 Milligram, Q6h	Not Reported
Dilaudid	C		4 Milligram	Not Reported
Dilaudid	C	Unknown	Unk	Not Reported
Abatacept	C		Unk	Not Reported
Leflunomide	C		Unk	Not Reported
Kineret	C		100 Milligram	Not Reported
Furosemide	C	Unknown	40 Milligram, Tid	Not Reported
Furosemide	C		40 Milligram, 3 Times/Wk	Not Reported
Furosemide	C	Unknown	Unk	Not Reported
Darifenacin Hydrobromide	C	Unknown	Unk Unk, As Required	Not Reported
Darifenacin Hydrobromide	C	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	C	Unknown	Unk Unk, As Necessary	Not Reported
Diphenhydramine Hydrochloride	C	Unknown	Unk	Not Reported
Norflex	C	Unknown	Unk Unk, Bid	Not Reported
Norflex	C		Unk	Not Reported
Pantoprazole Sodium	C	Unknown	Unk	Not Reported
Anakinra	C	Unknown	100 Milligram	Not Reported
Anakinra	C	Unknown	100 Milligram	Not Reported
Desoximetasone	C	Oral	Unk	Not Reported
Desoximetasone	C	Intramuscular	Unk	Not Reported
Desoximetasone	C	Unknown	Unk	Not Reported
Desoximetasone	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Codeine	C	Unknown	Unk	Not Reported
Hydromorphone	C	Unknown	Unk	Not Reported
Kadian	C	Unknown	Unk	Not Reported
Kenalog	C	Intra-articular	40 Milligram	Not Reported
Kenalog	C	Unknown	40 Milligram	Not Reported
Oxyneo	C	Unknown	Unk	Not Reported

	Restasis	C	Unknown	Unk	Not Reported
	Trimethoprim	C	Unknown	Unk	Not Reported
	Urispas	C	Unknown	200 Milligram	Not Reported
	Morphine Sulfate	C	Unknown	Unk	Not Reported
	Diphenhydramine	C	Unknown	Unk	Not Reported
	Dexamethasone	C	Unknown	Unk	Not Reported
	Dexamethasone	C	Oral	Unk	Not Reported
	Darifenacin	C	Unknown	Unk	Not Reported
	Dyclone	C	Unknown	Unk	Not Reported
	Pantoprazole Sodium Anhydrous	C	Unknown	Unk	Not Reported
	Plantago Ovata	C	Unknown	Unk	Not Reported
	Dyclonine Hydrochloride	C		Unk	Not Reported
	Orphenadrine	C	Unknown	1 Dosage Form, Bid	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Triamcinolone Acetonide	C	Intra-articular	40 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	12298212	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2016050673		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug	Enbrel			S	Unknown	25 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	25 Milligram, Q2wk		Amgen
	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Amgen
	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Unknown	25 Milligram		Amgen
	Etanercept			S	Unknown	25 Milligram, 2 Times/Wk		Amgen
	Etanercept			S	Unknown	50 Milligram, Qwk		Amgen
	Alendronate Sodium			S	Unknown	Unk		Not Reported

Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Alendronate Sodium	S	Unknown	70 Milligram, Qwk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira	S	Unknown	40 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	20 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	15.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12 Milligram	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Qwk	Not Reported
	Orencia	S	Unknown	780 Milligram, Qwk	Not Reported
	Orencia	S	Unknown	760 Milligram, Qwk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported

Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
Rituxan	S	Unknown	1000 Milligram, Bid	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Actemra	S	Unknown	360 Milligram, Q4wk	Not Reported
Actemra	S	Unknown	680 Milligram, Q4wk	Not Reported
Actemra	S	Unknown	2.68 Milligram, Q4wk	Not Reported
Actemra	S	Unknown	360 Milligram, Qmo	Not Reported
Actemra	S	Unknown	680 Milligram, Qmo	Not Reported
Actemra	S	Unknown	680 Milligram	Not Reported
Actemra	S	Unknown	360 Milligram, Qwk	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Qmo	Not Reported
Myochrysine	S	Intramuscular	25 Milligram, Qwk	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Q2wk	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Qwk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	20 Milligram	Not Reported
Tocilizumab	S	Unknown	380 Milligram	Not Reported
Tocilizumab	S	Unknown	360 Milligram, Qmo	Not Reported
Tocilizumab	S	Unknown	680 Milligram, Q4wk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	15 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	17.5 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	12.5 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	12 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Subcutaneous	70 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Oral	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Subcutaneous	10 Milligram, Qwk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	1000 Milligram, Bid	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Qd	Not Reported
Alendronic Acid	S	Unknown	70 Milligram, Qwk	Not Reported
Alendronic Acid	S	Unknown	70 Milligram, Qwk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Adalimumab	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Cimzia	S	Subcutaneous		Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	680 Milligram, Qmo	Not Reported
Simponi	S	Unknown	360 Milligram, Qmo	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Celebrex	S	Unknown	Unk	Not Reported
Fosamax	S	Unknown	70 Milligram, Qwk	Not Reported
Alendronate	C	Unknown	70 Milligram, Qwk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

Xeljanz	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	5 Milligram, Bid		Not Reported
Ciclosporin	C	Unknown	150 Milligram, Qd		Not Reported
Prednisone	C	Unknown	10 Milligram, Qd		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	10 Milligram, Q2h		Not Reported
Prednisone	C	Unknown	10 Milligram		Not Reported
Prednisone	C	Unknown	20 Milligram		Not Reported
Prednisolone	C		10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	12650430	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016089419		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Gold			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	11.2 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Qd		Not Reported

	Hydroxychloroquine	S	Unknown	200 Mg, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Mg, Bid	Not Reported
	Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	1 Gram, Qd	Not Reported
	Prednisone	C	Unknown	15 Milligram, Qd	Not Reported
	Prednisone	C			Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	12682616	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016018624		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Glucose Increased; Blood Pressure Increased; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Femur Fracture; Gait Disturbance; Gastric Disorder; Glycosylated Haemoglobin Increased; Heart Rate Increased; Hepatic Enzyme Increased; Infection; Joint	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	40 Milligram, Four Every One Week		Amgen
	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	50 Milligram, Qd		Amgen
	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	50 Milligram, 4 Every 1 Week		Amgen
	Actemra			S	Intravenous (not otherwise specified)	800 Milligram, Q4wk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported

Swelling; Loss Of Personal Independence In Daily Activities; Lymphocyte Count Increased; Malaise; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Nausea; Nephrolithiasis; Neutrophil Count Increased; Off Label Use; Osteopenia; Pain; Pain In Extremity; Peripheral Swelling; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Somnolence; Synovitis; Tooth Abscess; Treatment Failure; Visual Impairment; Weight Decreased; White Blood Cell Count Increased	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Arava	S	Unknown	Unk Unk, Qd	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Acetaminophen W/Diphenhydramine Hydrochloride	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	200 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Q4wk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Apo-Hydro	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
	Plaquenil	S	Unknown	200 Milligram, Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	200 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	5 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Subcutaneous	Unk	Not Reported
	Apo-Acetaminophen	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2000 Milligram, Unk	Not Reported

Sulfasalazine	S	Oral	2000 Milligram, Qd	Not Reported
Sulfasalazine	S	Oral	1000 Milligram, Qd	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Tylenol	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine	S	Oral	200 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Acetaminophen	S	Unknown	325 Milligram	Not Reported
Acetaminophen	S	Oral	650 Milligram	Not Reported
Acetaminophen	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Amaryl	S	Unknown	Unk	Not Reported
Otezla	S	Unknown	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	Unk, 4 Every 1 Week	Not Reported
Methotrexate	S	Unknown	Unk, Qwk	Not Reported
Methotrexate	S	Unknown	25 Dosage Form, Qwk	Not Reported
Methotrexate	S	Subcutaneous	20 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Meloxicam	C	Unknown	Unk, Qwk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Tylenol With Codeine No.3	C		Unk	Not Reported
Celebrex	C	Oral	200 Milligram, Bid	Not Reported
Hydromorphone Hcl	C		Unk	Not Reported
Acetaminophen And Codeine Phosphate	C	Unknown	Unk	Not Reported

Codeine	C	Unknown			Not Reported
Diphenhydramine	C	Oral	50 Milligram		Not Reported
Glyburide	C	Unknown	Unk		Not Reported
Hydrochlorothiazide	C	Unknown	Unk		Not Reported
Lipitor	C	Unknown	Unk		Not Reported
Metformin	C	Unknown	Unk Unk, Qd		Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram		Not Reported
Percocet [Oxycodone Hydrochloride;Paracetamol]	C	Unknown	Unk		Not Reported
Ramipril	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	12691420	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016405201		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	25 Milligram		Pfizer
	Sulfasalazine			S	Unknown	500 Milligram		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Xeljanz			S	Unknown	5 Milligram, Bid		Pfizer
	Minocycline			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	100 Milligram		Not Reported
	Azathioprine			S	Unknown	100 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Unk		Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo Hydroxyquine	S	Unknown	400 Mg, Unk	Not Reported
	Apo-Azathioprine	S	Unknown	100 Milligram	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Leflunomide	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	12973995	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016163638		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Synovitis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	20 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Leflunomide			S	Oral	20 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Gold			S	Unknown	50 Milligram, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	8 Milligram		Not Reported

Orencia	S	Unknown	750 Milligram, Unk		Not Reported
Methotrexate	S	Unknown	20 Milligram		Not Reported
Apo-Hydroxyquine	S	Unknown	400 Milligram		Not Reported
Apo-Hydroxyquine	S	Unknown	20 Milligram		Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
Meloxicam	C	Unknown	Unk		Not Reported

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

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

Hydroxychloroquine	C	Unknown	Unk		Not Reported
Cephalexine	C	Unknown	500 Milligram, Qid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	13814083	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017109326			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Rituxan			S	Unknown	1000 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Cortisone			C		10 Milligram, Qd		Not Reported
	Gold			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Desoximetasone			C	Unknown	10 Milligram, Qd		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Arthropathy; Contraindicated Product	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Subcutaneous	Unk		Not Reported

Administered; Drug Ineffective; Foot Operation; Ill-Defined Disorder; Infection; Limb Discomfort; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S	Subcutaneous	100 Milligram	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	300 Milligram, Qd	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 Gram, Cyclical	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	1.0 Dosage Form, Qd	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Apo-Hydroxyquine	S	Oral	Unk	Not Reported
	Gold	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	300 Milligram, Qd	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Rituximab	S	Intravenous drip	1 Gram	Not Reported
	Actonel	S	Unknown	35 Milligram, Qwk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	1.0 Dosage Form	Not Reported
	Risedronate	S	Unknown	Unk	Not Reported
	Risedronate	S	Unknown	35 Milligram, Qwk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	13859207	NON-EXPEDITED		HO	CA-AMGEN-CANSP2017119169			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Viral Infection	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Apo-Folic Acid			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	400 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Cymbalta			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

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

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

	Prednisone	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	2 Gram, Qd	Not Reported
	Xeljanz	C	Oral	5.0 Milligram, Bid	Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Intolerance; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported
	Kevzara			S	Unknown	20 Mg, Unk (Every 14 Days For Eight Weeks)		Not Reported
	Kevzara			S	Subcutaneous	20 Milligram, 1 Every 2 Weeks		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Esomeprazole Sodium			S	Unknown	Unk		Not Reported
	Sarilumab			S	Unknown	20 Milligram		Not Reported
	Sarilumab			S	Subcutaneous	20 Milligram, Q2wk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Nicotinamide			S	Unknown	Unk		Not Reported
	Thiamine Hydrochloride			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported

Act Esomeprazole	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd		Not Reported
Adalimumab	C	Unknown	Unk		Not Reported
Hydroxychloroquine	C	Unknown	400 Mg, Qd		Not Reported
Nexium	C	Unknown	Unk		Not Reported
Vitamin D	C		Unk		Not Reported
Magnesium	C	Unknown	Unk		Not Reported
Metformin	C	Unknown	Unk		Not Reported
Ergocalciferol	C	Unknown	Unk		Not Reported
Esomeprazole Magnesium Trihydrate	C		Unk		Not Reported
Dexpanthenol	C		Unk		Not Reported
Riboflavin	C		Unk		Not Reported
Vitamin A [Retinol]	C		Unk		Not Reported
Vitamin C [Ascorbic Acid]	C		Unk		Not Reported
Esomeprazole	C	Unknown			Not Reported

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

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

U.S. FOOD & DRUG ADMINISTRATION

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Enbrel			S	Unknown	50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	12.5 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	12.5 Mg, Qd		Pfizer
	Methotrexate Sodium			S	Unknown	Unk 2 Year		Pfizer
	Methotrexate Sodium			S	Intramuscular	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S	Intramuscular	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	12.5 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	12.5 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	40 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	12.5 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Intramuscular	12.5 Mg, Qd		Pfizer
	Methotrexate Sodium			S	Unknown	12.5 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk Unk, 1 Every 2 Years		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Arava			S	Oral	10 Mg, 2 Times/Wk		Not Reported
	Arava			S	Oral	10 Mg, 3 Times/Wk		Not Reported
	Arava			S	Oral	10 Mg, 1 Every 2 Days		Not Reported
	Arava			S	Oral	10 Mg, Qd 3 Months		Not Reported
	Arava			S	Oral	200 Mg, 2 Times/Wk		Not Reported
	Arava			S	Oral	10 Mg, Unk		Not Reported
	Arava			S	Unknown	200 Mg, 2 Times/Wk		Not Reported
	Arava			S	Oral	10 Mg, Q3wk		Not Reported

Arava	S	Unknown	10 Mg, 1x/Day	Not Reported
Arava	S	Oral	10 Mg, Bid	Not Reported
Arava	S	Oral	10 Mg, Q3mo	Not Reported
Arava	S	Unknown	200 Mg, Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Cyclical	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Plaquenil	S	Oral	200 Mg, Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
Rituxan	S	Unknown	1000 Mg, Cyclical	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Cyclical	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported

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

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

Drug Ineffective; Product Use In Unapproved Indication; Rheumatoid Arthritis; Uveitis	Cosentyx		S	Unknown	Unk	Novartis
	Simponi		S	Subcutaneous	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Cimzia		S	Subcutaneous	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Stelara		S	Subcutaneous	Unk	Not Reported
	Otezla		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	2 G, Qd	Not Reported
	Plaquenil		S	Unknown	400 Mg	Not Reported
	Methotrexate		C	Subcutaneous	20 Mg, Unk	Not Reported
	Methotrexate		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	15620611	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2018-CA-975882			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Drug Specific Antibody Present; Gastroenteritis Viral;	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Intravenous (not otherwise specified)			Barr
	Methotrexate			S	Subcutaneous			Barr
	Naproxen			S	Unknown			Teva
	Prednisone			S	Oral	10 Milligram Daily;		Actavis
	Prednisone			S	Oral	2 Dosage Forms Daily;		Actavis
	Prednisone			S	Oral	6 Milligram Daily;		Actavis

Gastroenteritis Viral; Human Anti-Human Antibody Test; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Product Use In Unapproved Indication; Product Use Issue; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Underdose; Vomiting; Wheelchair User	Prednisone	S	Unknown	100 Milligram Daily;	Actavis
	Prednisone	S	Unknown		Actavis
	Prednisone	S	Unknown		Actavis
	Prednisone	S	Oral	2.6 Milligram Daily;	Actavis
	Prednisone	S	Oral	2.6 Milligram Daily;	Actavis
	Prednisone	S	Oral	6 Milligram Daily;	Actavis
	Prednisone	S	Oral	6 Milligram Daily;	Actavis
	Prednisone	S	Oral	10 Milligram Daily;	Actavis
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	250 Milligram Daily;	Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S			Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported

Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Triamcinolone	S	Unknown		Not Reported
Triamcinolone	S	Unknown		Not Reported
Triamcinolone	S	Other		Not Reported
Triamcinolone	S	Intra-articular		Not Reported
Triamcinolone	S	Unknown		Not Reported
Triamcinolone	S	Unknown		Not Reported
Triamcinolone	S	Subcutaneous		Not Reported
Triamcinolone	S	Unknown		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S	Subcutaneous		Not Reported
Infliximab	S	Unknown		Not Reported
Gamastan S/D Medicinal Ingredient Also Know As Immuneglobulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
Hydroxychloroquine Sulfate Tablets, Usp	S	Oral	5 Mg/Kg Daily;	Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported

Enbrel	S	Unknown		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Kineret 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syri	S	Subcutaneous	50 Milligram Daily;	Not Reported
Kineret 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syri	S	Subcutaneous	50 Milligram Daily;	Not Reported
Kineret 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syri	S	Subcutaneous		Not Reported
Kineret 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syri	S	Subcutaneous		Not Reported
Humira (Adalimumab)	S	Subcutaneous		Not Reported
Humira (Adalimumab)	S	Unknown		Not Reported
Prednisone	S	Oral	6 Milligram Daily;	Not Reported
Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
Hydroxychloroquine	S	Oral	5 Milligram Daily;	Not Reported
Hydroxychloroquine	S			Not Reported
Hydroxychloroquine	S	Oral	5 Mg/Kg Daily;	Not Reported
Apo-Naproxen	S	Unknown		Not Reported
Apo-Naproxen	S	Oral	6 Milligram Daily;	Not Reported
Apo-Naproxen	S	Unknown		Not Reported
Anakinra	S	Subcutaneous	50 Milligram Daily;	Not Reported

	Anakinra	S			Not Reported
	Gammagard Liquid Also Know As Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Folic Acid	C			Not Reported

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

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

Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd		Not Reported
Methotrexate	C	Subcutaneous	20 Milligram, Qwk		Not Reported
Methotrexate	C	Subcutaneous	17.5 Milligram		Not Reported
Methotrexate	C	Subcutaneous	15 Milligram, Qwk		Not Reported
Methotrexate	C	Unknown	17.5 Milligram		Not Reported
Methotrexate	C	Subcutaneous	25 Milligram, Qwk		Not Reported
Methotrexate	C	Unknown	15 Milligram, Qwk		Not Reported
Methotrexate	C	Subcutaneous	17.5 Milligram, Qwk		Not Reported
Sulfasalazine	C	Oral	1 Gram, Qd		Not Reported
Xeljanz	C	Unknown	5 Milligram, Bid		Not Reported
Depo-Medrol	C		Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Tylenol 8 Hr Arthritis Pain	C	Unknown	Unk		Not Reported
Tylenol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	16439059	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2018011428		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	25 Milligram, Q2wk		Amgen
	Methotrexate Sodium			S	Unknown	15 Milligram		Not Reported
	Methotrexate Sodium			S	Unknown	15 Milligram		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	10 Milligram, 1x/Day	Not Reported
Leflunomide	S	Unknown	10 Milligram, 1x/Day	Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Leflunomide	S	Unknown	10 Milligram, Qd	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram 1 Every 6 Weeks	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram	Not Reported
Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
Aleve	C		Unk Unk, As Needed	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Arava	C	Unknown	Unk	Not Reported
Simponi	C	Subcutaneous	Unk	Not Reported
Simponi	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

	Bupropion	C	Unk	Not Reported
	Sulfasalazine	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	16882113	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05704		51 YR	Female	CAN

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

Methotrexate	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Methotrexate	S	Parenteral	Unknown		Not Reported
Methotrexate	S	Subcutaneous	Unknown		Not Reported
Methotrexate	S	Other	Unknown		Not Reported
Sulfasalazine	S	Unknown	Unknown		Not Reported
Hydroxychloroquine	S	Unknown	Unknown		Not Reported
Actemra	S	Unknown	Unknown		Not Reported
Actemra	S				Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Solution Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown Powder For Solution Intravenous		Not Reported
Xeljanz	S	Unknown	Unknown		Not Reported
Xeljanz	S	Oral			Not Reported
Tofacitinib	C	Unknown	Unknown		Not Reported

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

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

Actemra	S		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Hepatic Enzyme Abnormal; Pneumonia; Rheumatoid Arthritis; Vomiting	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Salazopyrin			S	Unknown	Unk		Not Reported

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

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

	Rituximab	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Infliximab	C	Unknown	Unk	Not Reported
	Penicillin /00000901/	C	Unknown	Unk	Not Reported

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

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

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

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

	Gabapentin	C	Unknown		Not Reported
	Amlodipine Besilate	C	Unknown		Not Reported

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Localised	Methotrexate			S	Subcutaneous			Barr

Infection; Malaise; Pleurisy; Pneumonia	Actemra		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17535930	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1304		46 YR	Female	CAN

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

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

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

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

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

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

Arthralgia; Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Off Label Use; Product Use Issue; Somnolence	Methotrexate		S	Subcutaneous		Barr
	Hydroxychloroquine		S	Oral		Not Reported
	Sulfasalazine		S	Oral	2 Gram Daily;	Not Reported

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

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

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

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

Renal Function Test Abnormal; Tremor	Diclofenac	C	Oral		Not Reported
	Diclofenac	C	Oral		Not Reported
	Diclofenac	C			Not Reported
	Sulfasalazine	C		2 Gram Daily;	Not Reported
	Tamsulosin Hydrochloride	C	Oral		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Mood Swings; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Indometacin			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Atorvastatin			S	Unknown	High Dose		Not Reported

	Clopidogrel		S	Unknown	Unk			Aurobindo
	Rivaroxaban		S	Unknown	Unk			Not Reported
	Hydroxychloroquine		S	Unknown	Unk			Not Reported
	Warfarin		S	Unknown	Unk			Not Reported
	Apixaban		S	Intracardiac	Unk			Not Reported

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

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

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

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

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

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

Methotrexate Sodium	S	Oral	20 Mg		Not Reported
Cyclosporine	S	Unknown			Novartis
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Humira	S	Subcutaneous			Not Reported
Chloroquine	S	Subcutaneous			Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Unk		Not Reported
Apo-Leflunomide	S	Oral			Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw		Not Reported
Orencia	S	Subcutaneous	125 Mg		Not Reported
Orencia	S	Subcutaneous	125 Mg		Not Reported
Plaquenil	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg		Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	S	Oral			Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported
Xeljanz Xr	C	Unknown			Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Pruritus;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Sulfasalazine	S	Unknown	Unk, Bid (2 Every 1 Days)		Not Reported
Xeljanz	S	Unknown	Unk		Not Reported

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

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

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

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

Prednisone	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Xeljanz	S	Oral		Not Reported
Atorvastatin Calcium	C	Unknown		Not Reported
Pantoloc [Pantoprazole]	C	Unknown		Not Reported

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

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

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

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

	Remicade	S	Unknown	Unk		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Gamma-Glutamyltransferase Increased; Hepatic Steatosis; Upper Respiratory Tract Infection	Methotrexate			S	Unknown	25 Mg, 1 Every 1 Week		Barr
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Rituximab			S	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

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

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

Sodium Aurothiomalate	S	Intramuscular	Not Reported
Xeljanz	S	Unknown	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Not Reported
Acetaminophen	C	Unknown	Not Reported
Anakinra	C	Unknown	Not Reported
Anakinra	C	Unknown	Not Reported
Ativan	C	Unknown	Not Reported
Benadryl /00000402/	C	Unknown	Not Reported
Codeine	C	Unknown	Not Reported
Darifenacin Hydrobromide	C	Unknown	Not Reported
Darifenacin Hydrobromide	C	Unknown	Not Reported
Darifenacin Hydrobromide	C	Unknown	Not Reported
Desoximetasone	C	Unknown	Not Reported
Desoximetasone	C	Unknown	Not Reported
Dexamethasone	C	Unknown	Not Reported
Dilaudid	C	Unknown	Not Reported
Diphenhydramine	C	Unknown	Not Reported
Dyclonine Hydrochloride	C	Unknown	Not Reported
Furosemide	C	Unknown	Not Reported
Furosemide	C	Unknown	Not Reported
Hydromorphone	C	Unknown	Not Reported
Kadian	C	Unknown	Not Reported
Loperamide	C	Unknown	Not Reported
Morphine Sulfate	C	Unknown	Not Reported
Norflex /00018303/	C	Unknown	Not Reported
Omnaris	C	Unknown	Not Reported
Oxyneo	C	Unknown	Not Reported
Pantoloc /01263204/	C	Unknown	Not Reported

	Pantoprazole Sodium	C	Unknown	Not Reported
	Restasis	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Trimethoprim	C	Unknown	Not Reported
	Urispas	C	Unknown	Not Reported
	Vagifem	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2020	12507876	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016083007		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Kineret			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	100 Milligram, Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

Methotrexate	C	Oral	25 Milligram, Qwk		Not Reported
Methotrexate	C	Unknown	25 Milligram, Qwk		Not Reported
Prednisone	C	Unknown	30 Milligram, Qd		Not Reported
Cortisone	C		Unk		Not Reported
Desoximetasone	C	Unknown	Unk		Not Reported
Methotrexate Sodium	C	Unknown	25 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2020	13436464	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016078528		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	125 Milligram, Qwk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Abatacept			S	Unknown	125 Milligram, Qwk		Not Reported
	Tofacitinib			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Gabapentin			C	Oral	400 Milligram, Tid 2		Not Reported

				Tablets In The Mornings. 1 Tablet In The Aftenoon And 2 Tablets In The Evenings	
	Gabapentin	C			Not Reported
	Xeljanz	C	Oral	5 Milligram, Qd	Not Reported
	Tylenol Arthritis	C	Unknown	650 Milligram, Qid	Not Reported
	Acetaminophen	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2020	13913466	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017129066		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Methotrexate			S	Oral	17.5 Milligram, Qwk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Bid		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product	Humira			S	Subcutaneous			Not Reported

Administered; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Enbrel		S	Unknown	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Xeljanz		C	Oral	Not Reported
	Simponi		C	Subcutaneous	Not Reported
	Arava		C		Not Reported
	Prednisone		C		Not Reported
	Aleve		C	Frequency-As Required	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2020	17433139	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2016091942		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Anxiety; Arthropathy; C-Reactive Protein; Chest Pain; Contraindicated Product Administered; Discomfort; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Dyspnoea; Fatigue;	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported

Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Pain; Pain; Pemphigus; Pericarditis; Pregnancy; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Therapy Non-Responder; Treatment Failure; Urticaria; Wound	Cimzia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	400 Milligram, Qd	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Atasol [Paracetamol]	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Diclofenac	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S			Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Milligram	Not Reported

Sulfasalazine	S	Oral	1000 Milligram, Bid	Not Reported
Sulfasalazine	S	Unknown	1 Gram, Bid	Not Reported
Sulfathalidine	S	Oral	500 Milligram	Not Reported
Sulfathalidine	S	Oral	1000 Milligram, Bid	Not Reported
Tofacitinib	S	Unknown	5 Milligram, Bid	Not Reported
Tofacitinib Citrate	S	Unknown	5 Milligram, Bid	Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Fosamax	S			Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram (1 Every 24 Hours)	Not Reported
Hydroxychloroquine Sulfate	S			Not Reported
Methotrexate	S	Unknown	25 Milligram (1 Every 24 Hours)	Not Reported
Methotrexate	S			Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
Reactine [Cetirizine Hydrochloride]	S			Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S			Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Vitamin C	C		Unk	Not Reported
Vitamin D	C		Unk	Not Reported
Glucosamine	C		Unk	Not Reported
Lansoprazole	C		30 Mg, Bid	Not Reported
Xeljanz	C	Unknown		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Limb Deformity; Musculoskeletal Pain; Pain; Pain In Extremity; Pruritus; Rash; Squamous Cell Carcinoma; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Citalopram Hydrobromide			C	Unknown			Not Reported
	Citalopram Hydrobromide			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

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

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

					otherwise specified)					
	Hydroxychloroquine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2020	15620376	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556697-00		39 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Therapeutic Product Effect Decreased; Viral Upper Respiratory Tract Infection	Humira			S	Subcutaneous			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Actemra			S	Unknown	Intravenous (Not Otherwise Specified)		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Unknown	Intravenous (Not Otherwise Specified)		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine			C				Not Reported
	Xeljanz			C	Oral			Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Nausea; Off Label Use;	Humira			S	Subcutaneous			Not Reported

Pain In Extremity; Peripheral Swelling; Product Use Issue; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Bearing Difficulty	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	11350033	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-PFIZER INC-2015262877		58 YR	Male	CAN

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

Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Photosensitivity Reaction; Product Use In Unapproved Indication; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stomatitis; Thrombosis; Urticaria	Enbrel	S	Subcutaneous	Unk	Pfizer
	Enbrel	S			Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S			Pfizer
	Methotrexate Sodium	S	Intra-arterial	Unk	Pfizer
	Methotrexate Sodium	S			Pfizer
	Sulfasalazine	S	Unknown	500 Mg, Unk	Pfizer
	Sulfasalazine	S			Pfizer
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg, Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Gold	S			Not Reported
	Kineret	S		Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S			Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported

Ilaris	S	Subcutaneous	Unk, Single Use Vial	Not Reported
Ilaris	S	Unknown	Unk, Single Use Vial	Not Reported
Ilaris	S	Intravenous (not otherwise specified)	Unk	Not Reported
Ilaris	S	Unknown	Unk (Powder For Injection)	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S			Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S			Not Reported
Arava	S	Unknown	Unk	Not Reported
Arava	S			Not Reported
Marijuana	S	Unknown	Unk	Not Reported
Minocycline	S	Unknown	Unk	Not Reported
Oxycodone	S	Unknown	10 Mg, Unk	Not Reported
Apo-Sulfasalazine	S		Unk	Not Reported
Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S			Not Reported
Hydroxychloroquine	S			Not Reported
Oxyquinoline Sulfate	S			Not Reported
Oxyquinoline Sulfate	S			Not Reported
Xeljanz	C	Oral	Unk Unk, Bid	Not Reported
Xeljanz	C	Unknown	5 Milligram, Q2wk	Not Reported
Lyrica	C	Oral	Unk	Not Reported
Rituximab W/Urelumab	C	Unknown	Unk	Not Reported
Prednisone	C		Unk Unk, Qd	Not Reported
Urelumab	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	11382867	EXPEDITED (15-DAY)		CA, DS, HO, OT	CA-PFIZER INC-2015267393		60 YR	Female	CAN

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

	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Oral	Unk	Not Reported
	Arava		C	Unknown	Unk	Not Reported
	Arava		C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	12091497	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016085227		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Product Use Issue; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Weekly (50 Milligram, Qwk)		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day (5 Milligram, Bid)		Pfizer
	Xeljanz			S		5 Ng, 2x/Day (5 Nanogram, Bid)		Pfizer
	Xeljanz			S		5 Mg, 2x/Day (5 Milligram, Bid)		Pfizer
	Sulfasalazine			S		Taken For 2 Years		Pfizer
	Sulfasalazine			S	Oral	500 Mg, 1x/Day (500 Milligram, Qd)		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk (25 Milligram)		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly (25 Milligram, Qwk)		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk (25 Milligram)		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	400 Mg, Taken For 2 Years		Not Reported

Plaquenil	S	Oral	200 Mg, 2x/Day (200 Milligram, Bid)	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S		40 Mg, 2x/Week (40 Milligram, Q2wk)	Not Reported
Humira	S		40 Mg, Unk (40 Milligram)	Not Reported
Humira	S	Subcutaneous	400 Mg, Unk (400 Milligram)	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Azathioprine	S		100 Mg, Unk (100 Milligram)	Not Reported
Apo-Azathioprine	S		Unk	Not Reported
Minocycline Hydrochloride	S	Unknown	50 Mg, Unk (50 Milligram)	Not Reported
Minocycline Hydrochloride	S		Unk	Not Reported
Minocycline	S		Unk	Not Reported
Azathioprine	S	Unknown	100 Mg, Unk (100 Milligram)	Not Reported
Arava	S	Oral	20 Mg, Weekly (20 Milligram, Qwk)	Not Reported
Arava	S	Oral	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Arava	S	Oral	20 Mg, 1x/Day (20 Milligram, Qd)	Not Reported
Apo-Minocycline	S		50 Mg, Unk	Not Reported
Orencia	S		Unk, Monthly (Qmo)	Not Reported

	Hydroxychloroquine Sulfate	S	Oral	400 Mg, Unk (400 Milligram)	Not Reported
	Hydroxychloroquine Sulfate	S		400 Unk	Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Not Reported
	Apo-Hydroxyquine	S		Unk	Not Reported
	Leflunomide	C	Unknown	20 Unk, Unk	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Amoxil	C	Unknown	Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Clavulin	C		Unk	Not Reported
	Amoxicillin Trihydrate And Clavulanate Potass	C	Unknown	Unk	Not Reported
	Bcg Vaccine	C	Intravenous (not otherwise specified)	Unk (Powder For Solution For Intravesical Use)	Not Reported
	Bcg Vaccine	C	Intravenous (not otherwise specified)	Unk (Powder For Solution For Intravesical Use)	Not Reported
	Bcg Vaccine	C	Unknown	Unk (Powder For Solution For Intravesical Use)	Not Reported
	Adalimumab	C		Unk	Not Reported
	Risedronate	C	Oral	35 Mg, Qwk	Not Reported
	Amoxicillin	C		Unk	Not Reported
	Amoxil [Amoxicillin Trihydrate]	C		Unk	Not Reported
	Hydroxychloroquine	C	Subcutaneous	400 Milligram	Not Reported
	Hydroxychloroquine	C	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine	C	Unknown	100 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	12185482	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016145185		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Creatinine	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer

Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel	S	Subcutaneous	50 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Subcutaneous	7.5 To 12.5 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Subcutaneous	7.5 To 12.5 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Subcutaneous	Unk, Weekly	Pfizer
	Methotrexate Sodium	S	Subcutaneous	Unk, Weekly	Pfizer
	Sulfasalazine	S	Oral	2.5 G, Daily	Pfizer
	Sulfasalazine	S	Oral	500 Mg, 1x/Day	Pfizer
	Gabapentin	S	Oral	100 Mg, 2x/Day	Pfizer
	Gabapentin	S	Unknown	100 Mg, 1 Every 2 Days	Pfizer
	Celebrex	S	Oral	Unk	Pfizer
	Celebrex	S		Unk, Occlusive Dressing Technique	Pfizer
	Fentanyl	S	Unknown	Unk	Pfizer
	Fentanyl	S	Unknown	Unk	Pfizer
	Celecoxib	S	Oral	Unk	Pfizer
	Xeljanz	S	Oral	5 Mg, 1x/Day	Pfizer
	Xeljanz	S	Oral	5 Mg, 2x/Day	Pfizer
	Xeljanz	S	Oral	5 Mg, Unk	Pfizer
	Plaquenil	S	Unknown	400 Mg, Daily (Qd)	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, Every 3 Weeks	Not Reported
	Myochrysine	S	Intramuscular	60 Mg, Cyclic Q3wk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Monthly	Not Reported
	Orencia	S	Subcutaneous	Unk, Weekly	Not Reported
	Orencia	S	Vaginal	750 Mg, Monthly	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
	Orencia	S	Intravenous (not	750 Mg, Cyclic Q3wk	Not Reported

		otherwise specified)		
Orencia	S	Vaginal	750 Mg, Monthly	Not Reported
Nortriptyline Hydrochloride/Perphenazine	S	Oral	10mg Tablets 1-3 Tablets Every Evening	Not Reported
Nortriptyline Hydrochloride/Perphenazine	S	Oral	10 Milligram	Not Reported
Actemra	S	Intravenous (not otherwise specified)	488 Mg, Monthly	Not Reported
Actemra	S	Oral	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	488 Mg, Cyclic Q4wk	Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Apo Fentanyl Matrix	S		Unk	Not Reported
Apo Celecoxib	S	Oral	Unk	Not Reported
Apo Gabapentin	S		Unk	Not Reported
Apo Gabapentin	S	Oral	100 Mg, 2x/Day	Not Reported
Arava	S	Oral	20 Mg, Qd	Not Reported
Fentanyl Matrix	S	Unknown	Unk Patch	Not Reported
Abatacept	S	Intravenous (not otherwise specified)	750 Mg, Monthly	Not Reported
Omega-3 [Salmo Salar Oil]	S		Unk	Not Reported
Omega-3 Fatty Acids	C		1200 Mg, 2x/Day	Not Reported
Multivitamin	C		Unk	Not Reported
Tecta	C		40 Mg, Daily	Not Reported
Diphenoxylate	C		2.5/0.25 Milligram, Qd	Not Reported
Vitamin D	C		400 Iu, Daily	Not Reported
Vitamin D	C		400 Df, 1x/Day	Not Reported
Actonel	C		36 Mg, Weekly	Not Reported
Perphenazine	C	Oral	10 Mg, Unk	Not Reported
Prednisone	C	Unknown	5 Mg, Daily	Not Reported

Prednisone	C		Unk5.0 Gbq, Qd	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Monthly	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, (Every Four Weeks)	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Q2wk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
Aclasta	C		Unk	Not Reported
Calcium	C		Unk	Not Reported
Fergon	C		300 Mg, Daily	Not Reported
Fergon	C		300 Mg, 1x/Day	Not Reported
Fergon	C		Unk	Not Reported
Tylenol	C	Oral	500 Mg 2 Tabs, 1x/Day	Not Reported
Tylenol	C	Oral	1000 Mg, 1x/Day	Not Reported
Nexium	C		40 Mg, 2x/Day	Not Reported
Trazodone Hcl	C	Oral	50 Mg, 1x/Day At Bedtime	Not Reported
Trazodone Hcl	C	Oral	50 Mg, 1x/Day	Not Reported
Nasonex	C	Nasal	2 Sprays, 2x/Day	Not Reported
Nasonex	C		Unk Unk, Bid (Spray Metered Dose)	Not Reported
Nasonex	C		2 Df, 2x/Day	Not Reported
Percocet	C		1 Tab 4-6h As Needed	Not Reported
Lomotil	C		2.5mg 3-4 Times/Day	Not Reported
Lomotil	C		2.5 Mg, Qd	Not Reported
Docosahexaenoic Acid	C	Unknown	Unk Unk, Qd	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Mg, 2x/Day	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg, 1x/Day	Not Reported
Diphenoxylate Hydrochloride	C		Unk, 1x/Day	Not Reported
Diphenoxylate Hydrochloride	C		Unk	Not Reported

Esomeprazole Magnesium Trihydrate	C	Unknown	40 Mg, 2x/Day	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Iu, 1x/Day	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C		Unk	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C		1 Df, Unk	Not Reported
Trazodone	C		Unk	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	40 Mg, 2x/Day	Not Reported
Esomeprazole	C		400 Mg, 2x/Day	Not Reported
Esomeprazole	C		Unk	Not Reported
Loperamide Hydrochloride	C		2.5 Mg, Unk	Not Reported
Ergocalciferol	C		400 Iu, 1x/Day	Not Reported
Ergocalciferol	C		Unk	Not Reported
Ergocalciferol	C	Unknown	Unk, 1x/Day	Not Reported
Tecta	C		40 Milligram, Qd	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Mg, Cyclic Qh	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Mg, Unk	Not Reported
Omega 3 2100	C		1200 Mg, 2x/Day	Not Reported
Omega 3 2100	C		Unk, Q2wk	Not Reported
Genteal [Hypromellose]	C		Unk	Not Reported
Fish Oil	C		1200 Mg, 2x/Day	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Ascorbic Acid	C		Unk	Not Reported
Biotin	C		Unk	Not Reported
Biotin	C		Unk	Not Reported
Nicotinamide	C		Unk	Not Reported
Pantoprazole	C		400 Mg, 1x/Day	Not Reported
Pantoprazole	C		40 Mg, 1x/Day	Not Reported
Pantoprazole	C		Unk	Not Reported

Pantoprazole	C		Unk	Not Reported
Pyridoxine Hydrochloride	C		Unk	Not Reported
Sodium	C		Unk	Not Reported
Thiamine Hydrochloride	C		Unk	Not Reported
Thiamine Hydrochloride	C		Unk	Not Reported
Vitamin A [Retinol]	C		Unk	Not Reported
Vit D3	C		Unk	Not Reported
Vitamin B12 [Cyanocobalamin]	C		Unk	Not Reported
Ferrous Fumarate	C		Unk	Not Reported
Ferrous Fumarate	C		Unk	Not Reported
Docosahexaenoic Acid/Eicosapentaenoic Acid	C		1200 Mg, 2x/Day	Not Reported
Docosahexaenoic Acid/Eicosapentaenoic Acid	C	Unknown	Unk Unk, Qd	Not Reported
Docosahexaenoic Acid/Eicosapentaenoic Acid	C	Unknown	Unk, Q2wk	Not Reported
Folic Acid	C		Unk	Not Reported
Folic Acid	C		Unk	Not Reported
Retinol Palmitate	C		Unk	Not Reported
Retinol Palmitate	C		Unk	Not Reported
Riboflavin	C		Unk	Not Reported
Riboflavin	C		Unk	Not Reported
Sodium Ascorbate	C		Unk	Not Reported
Thiamine Mononitrate	C		Unk	Not Reported
Vitamine C	C		Unk	Not Reported
Vitamin D3	C		Unk	Not Reported
Loperamide	C		Unk	Not Reported
Perfenazine	C	Oral	10 Mg, Unk	Not Reported
Atropine Sulfate/Diphenoxylate Hydrochloride	C		Unk	Not Reported
Nortriptyline	C		Unk	Not Reported
Oxycodone And Acetaminophen	C		Unk	Not Reported

Epa Dha 720	C		Unk	Not Reported
Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C		Unk	Not Reported
Thiamine	C		Unk	Not Reported
Vitamin E [Tocopherol]	C		Unk	Not Reported
Cholecalciferol	C		Unk	Not Reported
Ferrous Gluconate	C	Unknown	300 Milligram, Qd	Not Reported
Vitamin B3	C		Unk	Not Reported
Vitamin B1 [Thiamine]	C		Unk	Not Reported
Vitamin B6	C		Unk	Not Reported
Vitamin C [Ascorbic Acid]	C		Unk	Not Reported
Acetaminophen	C		Unk	Not Reported

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

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

Psychiatric Symptom; Rheumatoid Arthritis; Rib Fracture; Scar; Seizure; Sepsis; Spinal Deformity; Vomiting	Prednisone	S	Unknown	14 Mg, 1x/Day	Not Reported
	Dilaudid	C		4 Mg, 3x/Day	Not Reported
	Dilaudid	C			Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Furosemide	C		Unk, 1x/Day	Not Reported
	Hydromorph Contin	C		18 Mg, 3x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	12302274	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016221150		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling;	Enbrel			S	Unknown	25 Mg, Weekly		Pfizer
	Enbrel			S	Unknown	50 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk		Pfizer
	Enbrel			S	Unknown	25 Mg, 2x/Week		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	25 Mg, Unk (1 Every 2 Week)		Pfizer
	Enbrel			S	Unknown	50 Mg, Unk		Pfizer
	Etanercept			S	Unknown	25 Mg, 2x/Week		Pfizer
	Etanercept			S	Unknown	50 Mg, Weekly		Pfizer
	Celebrex			S		Unk		Pfizer
	Methotrexate Sodium			S	Unknown	12.5 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	12 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	12 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	12.5 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	15.5 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	15 Mg, Q4wk		Pfizer
	Methotrexate Sodium			S	Unknown	12 Mg, Q4wk		Pfizer
	Methotrexate Sodium			S	Unknown	10 Mg, Unk		Pfizer

Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	15 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	17.5 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	12.5 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	12 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	15 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	10 Mg, Q4wk	Pfizer
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	25 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	Unk	Pfizer
	Methotrexate Sodium	S	Oral	12.5 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	12.5 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Subcutaneous	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Subcutaneous	15 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Subcutaneous	15 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	70 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	12 Mg, Q4wk	Pfizer
	Methotrexate Sodium	S	Unknown	15 Mg, Q4wk	Pfizer
	Methotrexate Sodium	S	Unknown	15.5 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Subcutaneous	10 Mg, Q4wk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Q4wk	Pfizer

Methotrexate Sodium	S	Subcutaneous	12 Mg, Weekly	Pfizer
Sulfasalazine	S	Unknown	500 Mg, Unk	Pfizer
Sulfasalazine	S	Unknown	Unk	Pfizer
Infliximab Hospira	S	Intravenous (not otherwise specified)	Unk	Not Reported
Codeine	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	680 Mg, Monthly	Not Reported
Simponi	S	Unknown	360 Mg, Monthly	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
Leflunomide	S	Oral	20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Daily	Not Reported
Leflunomide	S		20 Mg, 5 Days Out Of 7	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	20 Unk, Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Every 2 Weeks	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Unknown	40 Mg, Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 1x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Daily	Not Reported
Rituxan	S	Unknown	1000 Mg, 2x/Day	Not Reported

Actemra	S	Unknown	360 Mg, Monthly	Not Reported
Actemra	S	Unknown	680 Mg, (Every 4 Weeks)	Not Reported
Actemra	S	Unknown	2.68 Mg, Q4wk	Not Reported
Actemra	S	Unknown	360 Mg, Qmo	Not Reported
Actemra	S	Unknown	680 Mg, Qmo	Not Reported
Actemra	S	Unknown	680 Mg, Monthly	Not Reported
Actemra	S	Unknown	680 Mg, Unk	Not Reported
Orencia	S	Unknown	780 Mg, Weekly	Not Reported
Orencia	S	Unknown	780 Mg, Weekly	Not Reported
Orencia	S	Unknown	760 Mg, Weekly	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Alendronate	S	Unknown	Unk	Not Reported
Alendronate	S	Unknown	70 Mg, Weekly	Not Reported
Alendronate	S	Unknown	70 Mg, Weekly	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Monthly	Not Reported
Myochrysine	S	Intramuscular	25 Mg, Weekly	Not Reported
Myochrysine	S	Parenteral	50 Mg, Monthly	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Cyclic (Once Every Two Weeks)	Not Reported
Myochrysine	S	Unknown	50 Mg, Monthly	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	Unk	Not Reported
Tocilizumab	S	Unknown	380 Mg, Unk	Not Reported
Tocilizumab	S	Unknown	360 Mg, Unk	Not Reported
Tocilizumab	S	Unknown	680 Mg, 1 Every 4 Week	Not Reported

Hydroxychloroquine	S	Oral	20 Mg, Unk	Not Reported
Hydroxychloroquine	S	Oral	200 Mg, 1x/Day	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Alendronic Acid	S	Unknown	70 Mg, Weekly	Not Reported
Rituximab	S	Unknown	1000 Mg, 2x/Day	Not Reported
Adalimumab	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Unknown	70 Mg, Weekly	Not Reported
Alendronate Sodium	C	Unknown	Unk	Not Reported
Alendronate Sodium	C	Unknown	70 Mg, Weekly	Not Reported
Prednisone	C	Unknown	10 Mg, 1x/Day	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	10 Mg, (Every 2 Hours)	Not Reported
Prednisone	C		10 Mg, Unk	Not Reported
Prednisone	C	Unknown	10 Mg	Not Reported
Prednisone	C	Unknown	20 Mg, Unk	Not Reported
Cyclosporin	C	Unknown	150 Mg, 1x/Day	Not Reported
Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	5 Mg, 2x/Day	Not Reported
Prednisolone	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	12338904	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2016241427		53 YR	Male	CAN

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

Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Rash; Skin Mass; Therapy Non-Responder	Enbrel	S	Subcutaneous	50 Mg, Once A Week	Pfizer
	Methotrexate Sodium	S	Oral	25 Mg, Monthly	Pfizer
	Methotrexate Sodium	S	Oral	25 Mg, Unk	Pfizer
	Tofacitinib Citrate	S	Oral	5 Mg, 2x/Day	Pfizer
	Xeljanz	S	Oral	5 Mg, Bid (2 Every 1 Day)	Pfizer
	Xeljanz	S	Oral	5 Mg, 2x/Day	Pfizer
	Xeljanz	S	Unknown	5 Mg, Bid	Pfizer
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Qd (1 Every 24 Hours)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Monthly	Not Reported
	Humira	S	Subcutaneous	40 Mg, Once Every Two Weeks	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Plaquenil	S	Oral	400 Mg, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Subcutaneous	50 Mg, Weekly (1 Every 1 Week(S))	Not Reported
	Apo-Hydroxyquine	S	Oral	400 Mg, Qd (1 Every 24 Hours)	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Qd	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Weekly	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Mg, Qd (1 Every 24 Hour)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Prednisone Acetate	S	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported

U.S. FOOD & DRUG ADMINISTRATION

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Thyroxine Decreased; Treatment Failure; Vomiting	Enbrel			S	Unknown	50 Milligram		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Milligram, Qd		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Infliximab			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	1 Dose		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Desoximetasone			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Methadone			S		Unk		Not Reported
	Rampril			S		Unk		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Estrogel	C	Unknown	0.6 %, Three Times A Day	Not Reported
	Estrogel	C	Unknown	1.0 Df Qd	Not Reported
	Estradiol	C		Unk, Tid	Not Reported
	Calcium	C		500 Milligram, Qd	Not Reported
	Xalatan	C	Ophthalmic	50 Microgram, Qd (50 Mcg 0.005% 1 Drop)	Not Reported
	Cosopt	C		Unk, 2x/Day	Not Reported
	Furosemide	C	Unknown	40 Milligram, Qd	Not Reported
	Valsartan	C	Unknown	320 Milligram, Qd	Not Reported
	Vitamin D	C		10000 Unit, Weekly	Not Reported
	Jampk20	C		1500 Mg, 1x/Day	Not Reported
	Zingiber Officinale	C	Oral	500 Mg, As Needed	Not Reported
	Dorzolamide Hcl And Timolol Maleate	C	Unknown	Unk, 2x/Day	Not Reported
	Ergocalciferol	C	Unknown	Unk, Weekly	Not Reported
	Ergocalciferol	C	Unknown	Unk, Qd	Not Reported
	Morphine	C	Unknown	Unk Unk, As Necessary	Not Reported
	Potassium Chloride	C	Unknown	1500 Mg, 1x/Day (Qd)	Not Reported
	Gravol Ginger	C	Oral	500 Milligram, As Needed	Not Reported
	Baclofen	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	12659993	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016335872		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral;	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	1 G, Qd		Pfizer
	Actemra			S	Unknown	Unk		Not Reported

Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Mg, 2x/Day	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	20 Mg, 1x/Day	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, 2x/Day	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	11.2 Milligram, Qd	Not Reported
	Plaquenil	S	Unknown	200 Mg, 2x/Day(Bid)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, 2x/Day	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	1 Gram, Qd	Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Prednisone	C	Unknown	15 Mg, Daily (Qd)	Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Condition Aggravated; Drug Ineffective; Infection;	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported

Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Synovitis; Treatment Failure; Vomiting	Gold	S	Unknown	50 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	8 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	20 Mg, Qd	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Mg, Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
	Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Meloxicam	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13128781	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017005116		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	25 Mg, 2 Times/Wk		Amgen
	Enbrel			S	Unknown	25 Mg, Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	25 Mg, Bid		Amgen
	Arava			S	Unknown			Not Reported
	Rituximab			S	Unknown	1 Gram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Unknown	15 Mg, Qwk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Not Reported

Anakinra	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Q2wk	Not Reported
Humira	S	Unknown	40 Mg, Unk	Not Reported
Humira	S	Unknown	40 Mg, Cyclical	Not Reported
Humira	S	Unknown	40 Mg, Q2wk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Q6wk	Not Reported
Remicade	S	Unknown	300 Mg, Unk	Not Reported
Remicade	S	Unknown	300 Mg, Cyclical	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Bid	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	200 Mg, Bid	Not Reported
Apo-Hydroxyquine	S	Unknown	20 Milligram, Qd	Not Reported
Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Oral	200 Mg, Bid	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	200 Mg, Bid	Not Reported
Methotrexate	S	Unknown	20 Mg, Qwk	Not Reported
Methotrexate	S	Unknown	15 Mg, Qwk	Not Reported
Methotrexate	S	Unknown	20 Mg, Unk	Not Reported
Methotrexate	S	Unknown	200 Mg, Qwk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Sulfasalazine	C	Unknown	1 G, Bid	Not Reported

	Wellbutrin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13549390	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017071781		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Supeudol			C	Unknown	5 Mg, As Necessary		Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13761472	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017105360		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Celebrex			C		Unk, As Necessary		Not Reported
	Xeljanz			C		Unk		Not Reported

	Prednisone	C	Unk Unk, As Necessary	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13805299	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017112357		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Blood Pressure Increased; Cataract; Cataract Operation; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Glaucoma Surgery; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	1 Dosage Form, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Lyrica			C	Oral	Unk		Not Reported
	Lyrica			C	Unknown	Unk		Not Reported
	Prednisone			C	Oral	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Arava			C		Unk		Not Reported
	Codeine			C	Unknown	Unk		Not Reported

	Tylenol [Paracetamol]			C	Unknown	Unk				Not Reported

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

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

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

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

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

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

	Abatacept	C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13909412	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017128000		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Dosage Form, Q2wk		Not Reported
	Orencia			S	Unknown	40 Milligram, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	2.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	15 Milligram, Qwk		Not Reported

Methotrexate	S	Unknown	Unk	Not Reported
Folic Acid	C		Unk	Not Reported
Folic Acid	C		2.5 Milligram, Qd	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Pantoprazol	C	Unknown	Unk	Not Reported
Pantoprazole Magnesium	C	Oral	40 Milligram, Qd	Not Reported
Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
Tenofovir Disoproxil [Tenofovir Disoproxil Fumarate]	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Zopiclone	C	Unknown	7.5 Milligram, Qd	Not Reported
Zopiclone	C	Unknown	Unk	Not Reported
Tenofovir	C		Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Oral	300 Milligram, Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	300 Milligram, Unk	Not Reported
Pantoprazole Sodium	C	Unknown	Unk	Not Reported
Pantoprazole Bluefish	C	Unknown	Unk	Not Reported
Pantoprazole	C		Unk	Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk (Single Use Prefilled		Not Reported

Factor Positive				Syringe)	
	Cimzia	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Imuran	C	Unknown	Unk	Not Reported
	Arthrotec	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Ergocalciferol	C		Unk	Not Reported
	Azathioprine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13926256	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017375036		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper;	Enbrel			S	Unknown	50 Mg, Qwk		Pfizer

Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Methotrexate Sodium	S	Oral	17.5 Mg, Qwk	Pfizer
	Arava	S	Unknown	20 Mg, Qd	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q2wk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Mg, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Bid	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Bid	Not Reported
	Sulfasalazine	C		Unk	Not Reported

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14185061	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017170005		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis; Toe Amputation	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	200 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram, Bid		Not Reported
	Folic Acid			C		Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Restasis			C	Unknown	Unk		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	25 Milligram, Q2wk		Amgen
	Enbrel			S	Unknown	25 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	25 Milligram		Amgen
	Enbrel			S	Unknown	25 Milligram, Cyclical		Amgen

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14190825	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017490362		57 YR	Female	CAN

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

Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Inappropriate Schedule Of Product Administration; Injury; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis	Enbrel	S	Subcutaneous	50 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Oral	25 Milligram, Qwk	Pfizer
	Sulfasalazine	S	Oral	1000 Milligram, Bid	Pfizer
	Actemra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Hydroxyquine	S	Oral	200 Mg, Bid	Not Reported
	Folic Acid	C		Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Restasis	C	Unknown	Unk (Emulsion)	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14216870	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017174939			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Actemra			S	Subcutaneous	Unk Unk, Qwk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Meloxicam			S	Oral	7.5 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Mobicox			S	Oral	7.5 Milligram, Qd		Not Reported

	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Sulfasalazine	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14217819	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017175088		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Milligram, Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Bid		Not Reported
	Plaquenil			S	Oral	200 Milligram, Bid		Not Reported
	Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	10000 Milligram, Bid		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14224287	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017175535		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Drug	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported

Ineffective; Joint Swelling; Leukopenia; Off Label Use; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Qd	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Off Label Use; Oral Discomfort; Treatment Failure; Uveitis	Enbrel			S	Unknown	Unk		Amgen
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	10 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	40 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Tofacitinib			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Rabeprazole Sodium			C	Oral	20 Milligram, Qd		Not Reported

	Prednisone	C	10 Milligram	Not Reported

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

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

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

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

Methotrexate	S	Subcutaneous	20 Mg, Qwk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Apo-Leflunomide	S	Unknown	Unk		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported
Leflunomide	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	20 Mg, Qd		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15286198	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016077975		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Apo Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Injection		Novartis
	Cyclosporine			S	Subcutaneous	Unk		Novartis
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituximab			S	Oral	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxyquinoline Sulfate			S	Oral	Unk		Not Reported
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported

	Xeljanz	C	Unknown	2 Ot, Qd		Not Reported
	Xeljanz	C	Oral	10 Mg, Qd		Not Reported
	Xeljanz	C	Unknown	2 Df, Qd		Not Reported

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

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

U.S. FOOD & DRUG ADMINISTRATION

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15583667	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017372752		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Tremor	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	2.5 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	1 Df, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	10 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	15 Milligram, Qwk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Dosage Form, Q2wk		Not Reported
	Orencia			S	Unknown	40 Milligram, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Folic Acid			C	Oral	2.5 Milligram, Qd		Not Reported

	Folic Acid	C		Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Pantoprazol	C	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	C	Oral	40 Milligram, Qd	Not Reported
	Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
	Tenofovir Disoproxil [Tenofovir Disoproxil Fumarate]	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Zopiclone	C	Unknown	7.5 Mg, Daily	Not Reported
	Zopiclone	C	Unknown	Unk	Not Reported
	Tenofovir	C		Unk	Not Reported
	Tenofovir Disoproxil Fumarate	C	Oral	300 Milligram, Unk	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	Unk	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	300 Milligram, Unk	Not Reported
	Pantoprazole Sodium	C	Unknown	Unk	Not Reported
	Pantoprazole Bluefish [Pantoprazole Sodium Sesquihydrate]	C	Unknown	Unk	Not Reported
	Pantoprazole	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15585218	EXPEDITED (15-DAY)		DS, HO, OT	CA-ABBVIE-18K-028-2540122-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Disability; Drug Ineffective; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S				Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Gp2013		Not Reported
	Rituximab			S	Unknown			Not Reported

Site Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use In Unapproved Indication; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Leflunomide	S	Oral	Not Reported
	Leflunomide	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S		Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S		Not Reported
	Abatacept	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Disorder; Bronchiectasis; Bursitis; Bursitis Infective; Crying; Erythema; Gastrointestinal Disorder; Infection; Inflammation; Joint Range Of Motion Decreased; Leg Amputation; Localised Infection; Osteoporosis; Peripheral Vascular Disorder; Photosensitivity	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Reaction; Pneumonia; Renal Failure; Respiratory Tract Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Swelling; Synovitis; Tenosynovitis; Therapeutic Product Effect Incomplete	Azathioprine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Acidophilus	C		Not Reported
	Aspirin	C		Not Reported
	Calcium	C		Not Reported
	Deflazacort	C		Not Reported
	Dilaudid	C		Not Reported
	Ergocalciferol	C		Not Reported
	Hydromorphone Hydrochloride	C	Intramuscular	Not Reported
	Januvia	C		Not Reported
	Kenalog	C	Intra-articular	Not Reported
	Lidocaine	C	Topical	Not Reported
	Metronidazole	C		Not Reported
	Nitroglycerin	C		Not Reported
	Pantoloc	C		Not Reported
	Pregabalin	C		Not Reported
	Pregabalin	C		Not Reported
	Pregabalin	C		Not Reported
	Risedronate	C		Not Reported
	Rosuvastatin Calcium	C		Not Reported
	Salbutamol	C		Not Reported
	Triamcinolone	C		Not Reported
	Tylenol	C		Not Reported
	Xeljanz	C	Oral	Not Reported
	Triamcinolone Acetonide	C		Not Reported
	Salicylic Acid	C		Not Reported
	Rosuvastatin	C	Unknown	Not Reported
	Risedronate Sodium	C	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported

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

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

Drug Ineffective; No Adverse Event	Enbrel	S	Subcutaneous	Unk	Amgen
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
	Orencia	S	Oral	200 Milligram, Bid	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Prednisone	C		Unk	Not Reported
	Methotrexate	C	Oral	20 Milligram, Qwk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Condition Aggravated; Drug Intolerance; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, Bid		Pfizer
	Adalimumab			S	Unknown	Unk		Not Reported
	Act Esomeprazole			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Esomeprazole Sodium			S	Unknown	Unk		Not Reported
	Folic Acid			S		Unk		Not Reported

Nicotinamide	S		Unk	Not Reported
Azathioprine	S		Unk	Not Reported
Thiamine Hydrochloride	S		Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Actemra	S	Subcutaneous	162 Mg, Qwk, Six Months	Not Reported
Kevzara	S		20 Mg, Unk (Every 14 Days For Eight Weeks)	Not Reported
Kevzara	S	Subcutaneous	20 Milligram, 1 Every 2 Weeks	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Mg, 1x/Day	Not Reported
Sarilumab	S	Subcutaneous	20 Mg, 2x/Week	Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Riboflavin	C		Unk	Not Reported
Vitamin A [Retinol]	C		Unk	Not Reported
Vitamin C [Ascorbic Acid]	C		Unk	Not Reported
Vitamin D [Ergocalciferol]	C	Unknown	Unk	Not Reported
Dexpanthenol	C		Unk	Not Reported
Esomeprazole Magnesium Trihydrate	C		Unk	Not Reported
Nexium [Esomeprazole Magnesium]	C	Unknown	Unk	Not Reported
Esomeprazole	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15704441	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018174077			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported

Orencia	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	200 Mg, Bid	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Kevzara	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Acetaminophen	C		650 Milligram, Bid	Not Reported
Aluminium Acetate W/Benzethonium Chloride	C		Unk	Not Reported
Atacand	C		Unk	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Hydrodiuril	C	Unknown	Unk	Not Reported
Neurontin	C	Unknown	600 Milligram, Tid	Not Reported
Premarin	C	Unknown	Unk	Not Reported
Tylenol	C	Unknown	650 Mg, Bid	Not Reported
Aluminium Acetate	C	Unknown	Unk	Not Reported
Benzethonium Chloride	C	Unknown	Unk	Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported

Etanercept	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Fosamax	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Prednisone	S	Unknown	Not Reported
Reactine[Cetirizine Hydrochloride]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16120373	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019045643		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qd		Not Reported

Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Unknown	Unk (Tablets)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Sulfasalazine	S	Oral	500 Milligram, Qd	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported
Orencia	S	Unknown	75 Milligram, Qmo	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram, Qwk	Not Reported
Myochrysine	S	Intramuscular	25 Milligram, Qwk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Plaquenil S	C		Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Risedronate	C	Oral	35 Milligram, Qwk	Not Reported
Cimzia	C	Subcutaneous	200 Milligram	Not Reported

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

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

Bifidumbacterin	C		Not Reported
Celebrex	C		Not Reported
Loperamide	C		Not Reported
Methotrexate	C		Not Reported
Pantoprazole	C		Not Reported
Xeljanz	C		Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody	Aleve			S	Unknown	Unk		Bayer
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Kineret			S	Subcutaneous	50.0 Mg, Qd		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Oral	5.0 Mg, Bid		Not Reported
	Enbrel			S	Subcutaneous	25.0 Mg, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, 4iw		Not Reported
	Enbrel			S	Subcutaneous	25 Unk		Not Reported
	Gammagard			S	Intravenous (not otherwise specified)	70.0 G		Not Reported

Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting; Wheelchair User	Hydroxychloroquine	S	Oral	5.0 Mg, Qd	Not Reported
	Infliximab	S	Unknown	5.0 Mg	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3.0 Mg, Ow	Not Reported
	Methotrexate	S	Subcutaneous	15.0 Mg, Ow	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250.0 Mg, Q1mon	Not Reported
	Prednisone	S	Oral	3.0 Mg, Bid	Not Reported
	Prednisone	S	Oral	5.0 Unk	Not Reported
	Sulfasalazine	S	Oral	250.0 Mg, Qd	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280.0 Mg, Q2wk	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Ow	Not Reported
	Triamcinolone	S	Subcutaneous	25.0 Mg, Q2wk	Not Reported
	Triamcinolone Acetonide	S	Unknown	Unk	Not Reported
	Triamcinolone Acetonide	S			Not Reported
	Triamcinolone Acetonide	S			Not Reported
	Gamastan	S		70.0 G	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5.0 Mg/Kg, Qd	Not Reported
	Naproxen	S	Unknown		Not Reported
	Triamcinolone Hexacetonide	S	Unknown		Not Reported
	Immunoglobulin I.V	S	Intravenous (not otherwise specified)	70.0 G	Not Reported
	Triamcinolone Hexacetonide	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16330442	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019077665			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Subcutaneous	Unk		Not Reported

Personal Independence In Daily Activities; Therapeutic Response Decreased	Apo-Leflunomide		S	Unknown	20 Milligram, Qd	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Methotrexate		S	Unknown	20 Milligram, Qwk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	400 Milligram, Qd	Not Reported
	Sulfasalazine		S	Unknown	2 Gram, Qd	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram, Qd	Not Reported
	Xeljanz		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16470848	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2018036164		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	25 Milligram, Q2wk		Pfizer
	Methotrexate Sodium			S	Unknown	15 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	15 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	10 Milligram, 1x/Day		Not Reported
	Leflunomide			S	Unknown	10 Milligram, 1x/Day		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Hydroxychloroquine	S	Unknown	200 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	10 Milligram, Qd	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram 1 Every 6 Weeks	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram	Not Reported
Aleve	C		Unk Unk, As Needed	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Arava	C	Unknown	Unk	Not Reported
Simponi	C	Subcutaneous	Unk	Not Reported
Simponi	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Bupropion	C		Unk	Not Reported
Sulfasalazine	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16471566	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017312936		65 YR	Female	CAN

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

Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel	S	Unknown	25 Mg, 2x/Week	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Plaquenil	S	Oral	Unk	Not Reported
	Remicade	S	Unknown	300 Mg, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	1000 Mg, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Desoximetasone	C	Unknown	10 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16483146	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2017349309		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Infection; Limb Discomfort; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	17.5 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported

Arava	S	Oral	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	1.0 Dosage Form, Qd	Not Reported
Hydroxychloroquine	S	Oral	300 Mg, 1x/Day	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1 G, Cyclic	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Apo-Hydroxyquine	S	Oral	Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Plaquenil S	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	20 Mg, 1 Every 1 Hour(S)	Not Reported
Leflunomide	S	Unknown	1.0 Dosage Form	Not Reported
Leflunomide	S	Oral	20 Mg, 1x/Day	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	300 Mg, 1x/Day	Not Reported
Actonel	S	Unknown	35.0 Mg, Weekly	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
Risedronate	S	Unknown	Unk	Not Reported
Risedronate	S		35 Mg, Weekly	Not Reported
Methotrexate	C		Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16628388	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2863507-00		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16793789	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018056893		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	50 Milligram, Qd		Amgen
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Unk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Neoral			S	Subcutaneous	Unk		Not Reported
	Neoral			S	Unknown	Unk		Not Reported
	Neoral			S	Oral	Unk		Not Reported
	Neoral			S	Subcutaneous	Unk		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Enbrel			S	Unknown	50 Milligram		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Ergocalciferol			C		Unk Unk, Qwk		Not Reported

	Dorzolamide Hydrochloride And Timolol Maleate	C	Unknown	Unk Unk, Bid	Not Reported
	Estrogel	C		0.6 Percent, Tid	Not Reported
	Furosemide	C	Unknown	40 Milligram, Qd	Not Reported
	Morphine	C	Unknown	Unk	Not Reported
	Potassium Chloride	C	Unknown	1500 Milligram, Qd	Not Reported
	Valsartan	C		320 Milligram, Qd	Not Reported
	Xalatan	C		50 Microgram, Qd	Not Reported
	Zingiber Officinale	C	Oral	500 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16807532	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019147890			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	8 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qd		Not Reported
	Orencia			S	Unknown	750 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	50 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported
	Gold			S	Unknown	50 Milligram		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16848358	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019155529			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16948402	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2972424-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Leukoplakia Oral; Lung Disorder; Pneumonia; Pyrexia	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17036954	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019493883		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Asthma; Atelectasis; Blood Disorder; Blood Immunoglobulin E Increased; Bronchial Wall Thickening; Bronchiolitis; Condition Aggravated; Cough; Dysphonia; Dyspnoea; Eosinophil Count Increased; Eosinophilic Granulomatosis With Polyangiitis; Fungal Infection; Infection Parasitic; Inflammation; Malaise; Oropharyngeal Pain; Pneumonia; Pneumonitis; Productive Cough; Secretion Discharge; Sinusitis; Skin Disorder; Sleep Disorder Due To A General Medical Condition; Spirometry Abnormal; Suprapubic Pain; Systemic Inflammatory Response Syndrome; Therapeutic Product Effect Incomplete; Underweight; Vasculitis; Weight Decreased; Wheezing	Pantoloc			S	Unknown	40 Milligram		Pfizer
	Omnaris			S	Unknown	50 Microgram		Not Reported
	Alvesco			S	Unknown	200 Microgram, Qd		Not Reported
	Ivermectin			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	5 Milligram		Not Reported
	Prednisone			S	Oral	50 Milligram		Not Reported
	Salbutamol Sulfate			S	Unknown	100 Microgram		Not Reported
	Umeclidinium Bromide			S	Unknown	62.5 Microgram		Not Reported
	Zenhale			S	Unknown	2 Df, Bid		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17038283	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1116759		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abscess; Adrenal Insufficiency; Alanine Aminotransferase Increased; Ascites; Asthenia; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Potassium Decreased; Blood Pressure Diastolic Abnormal; Blood Pressure Increased; Congestive Hepatopathy; Depression; Diverticulitis; Endometrial Disorder; Enterococcus Test Positive; Fibrosis; Gamma-Glutamyltransferase Increased; Gastrointestinal Disorder; Generalised Oedema; Heart Rate Increased; Herpes Zoster; Hypersensitivity; Hypoglycaemia; Hypotension; Increased Appetite; Influenza; Infusion Related Reaction; Injection Site Extravasation; Intensive Care Unit Acquired Weakness; Intervertebral Disc Protrusion; Joint Effusion; Joint Swelling; Micturition Disorder; Myelopathy; Myopathy; Nasopharyngitis; Nausea; Nerve Compression; Neuropathy Peripheral; Neutropenia; Osteoarthritis;	Furosemide			S	Unknown			Ivax
	Mycophenolate Mofetil			S	Unknown	1000 Milligram Daily;		Teva
	Mycophenolate Mofetil			S	Unknown	1000 Milligram Daily;		Teva
	Piperacillin Sodium /Tazobactam Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown	10 Milligram Daily;		Actavis
	Prednisone			S	Unknown			Actavis
	Rosuvastatin Calcium			S	Unknown			Teva
	Vancomycin Hydrochloride			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram Daily;		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram Daily;		Not Reported
	Ceftazidime			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Actonel			C				Not Reported
	Apo Amlo			C				Not Reported
	Apo-K			C				Not Reported
	Diphenhydramine Hydrochloride			C	Oral			Not Reported
	Epoetin Alfa			C				Not Reported
	Escitalopram			C	Unknown			Not Reported
	Hydrochlorothiazide			C				Not Reported
	Ventolin [Salbutamol Sulfate]			C				Not Reported
	Tylenol [Paracetamol]			C				Not Reported
	Slow-K			C				Not Reported
	Risedronate			C				Not Reported
	Pantoprazole			C				Not Reported
	Pantoloc [Pantoprazole]			C		40 Milligram Daily;		Not Reported
	Metoprolol			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Metformin			C				Not Reported

Pancytopenia; Peripheral Sensorimotor Neuropathy; Peritonitis; Pneumonia; Pseudomonal Bacteraemia; Rheumatoid Arthritis; Septic Shock; Therapeutic Response Decreased; Vomiting; Weight Decreased; Weight Increased	Kcl	C	Not Reported
	Januvia	C	Not Reported
	Insulin Lispro	C	Not Reported
	Hydroxychloroquine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17205986	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA353135		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Sodium Aurothiomalate			S	Subcutaneous	Unk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Arava			S	Oral	10 Mg		Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Leflunomide			S		10 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Hydroxychloroquine Sulfate			S		300 Mg		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg, Qw		Not Reported
	Methotrexate			S		12.5 Df		Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Plaquenil			S				Sanofi
	Sulfasalazine			S				Not Reported
	Actemra			S		Unk		Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous	25 Mg		Not Reported
	Enbrel			S	Unknown	50 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S	Subcutaneous	25 Mg		Not Reported

	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous	250 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Q6w	Not Reported
	Rituximab	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
	Bifidobacterium Bifidum	C			Not Reported
	Celebrex	C			Not Reported
	Loperamide	C			Not Reported
	Pantoprazole	C			Not Reported
	Prednisone	C		40 Mg	Not Reported
	Prednisone	C		250 Unk	Not Reported
	Simponi	C			Not Reported
	Sulfasalazine	C			Not Reported
	Wellbutrin	C			Not Reported
	Xeljanz	C	Oral	5 Mg	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	C		200 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17211808	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA354607			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis;	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Methotrexate			S		25 Mg, Qw		Not Reported
	Methotrexate			S		20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Plaquenil			S		200 Mg		Sanofi
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	500 Mg Bid		Not Reported

Sleep Disorder Due To General Medical Condition, Insomnia Type	Prednisone	S		20 Mg, Qd	Not Reported
	Prednisone	S		20 Mg, Qd	Not Reported
	Arava	S		10 Mg, Qd	Sanofi
	Sodium Aurothiomalate	S		Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Bim	Not Reported
	Actemra	S			Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Orencia	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	2 G, Q6m	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17215414	EXPEDITED (15-DAY)		OT	CA-SA-2019SA353952		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Visual Impairment	Sodium Aurothiomalate			S		Unk		Not Reported
	Sodium Aurothiomalate			S		Unk/Gold		Not Reported
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Plaquenil			S	Oral	400 Mg, Qd		Sanofi
	Plaquenil			S	Unknown	400 Mg, Qd		Sanofi
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Orencia	S	Subcutaneous	125 Mg, Qw		Not Reported
Orencia	S	Intravenous (not otherwise specified)	125 Mg, Qw		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Acetaminophen	C	Unknown	Unk		Not Reported
Depo-Medrol	C		Unk		Not Reported
Methotrexate	C	Subcutaneous	15 Mg, Qw		Not Reported
Methotrexate	C	Unknown	15 Mg, Qw		Not Reported
Methotrexate	C	Subcutaneous	17.5 Mg		Not Reported
Methotrexate	C	Unknown	17.5 Mg		Not Reported
Methotrexate	C	Subcutaneous	25 Mg, Qw		Not Reported
Methotrexate	C	Subcutaneous	20 Mg, Qw		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Sulfasalazine	C	Oral	1 G, Qd		Not Reported
Tylenol	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17427584	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1186381		11 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cryptosporidiosis Infection; Hypogammaglobulinaemia; Leukopenia; Neutropenia; Weight Decreased	Hydroxychloroquine			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17434479	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019415671			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17449016	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007838		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Finger Deformity; Foot Deformity; Gastrointestinal Disorder; Loss Of Personal Independence In Daily Activities; Nausea	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Methotrexate			S	Parenteral	15 Mg, Unk		Not Reported
	Methotrexate			S	Parenteral	25 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk, Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17449345	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007801			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Aleve			C	Unknown	Unk		Not Reported
	Enbrel			C	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported
	Sulfasalazine			C	Oral	2000 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17482799	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008186		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; C-Reactive Protein; Drug Intolerance; Fatigue; Finger Deformity; Gastrointestinal Disorder; Hypersensitivity; Nausea; Pain; Paraesthesia; Rheumatoid Arthritis; Swelling; Swollen Joint Count; Therapeutic Product Effect Incomplete; Urticaria	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Enbrel			S	Unknown	Unk, Unknown		Not Reported
	Methotrexate			S	Unknown	Unk, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported
	Sarilumab			C	Unknown	Unk, Unknown		Not Reported
	Xeljanz			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17485926	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008204			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide		S	Unknown	Unk	Apotex
	Actemra		S	Unknown	Unk	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Plaquenil /00072602/		S	Unknown	Unk	Not Reported
	Remicade		S	Unknown	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17542948	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566947			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17542960	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566909		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Dequalinium Chloride			C				Not Reported
	Mefenamic Acid			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543158	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022567		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	25 Milligram, Bid		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	200 Milligram, Bid		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown	1 Gram, Bid		Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543200	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022609			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

	Cortisone Acetate	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543230	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566985			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

	Sulfate]			
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543233	EXPEDITED (15-DAY)		DE, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1339		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Chills; Erythema; Fatigue; Hypotension; Klebsiella Infection; Leukopenia; Multiple Organ Dysfunction Syndrome; Odynophagia; Product Use Issue; Rash; Rash Vesicular; Skin Lesion; Thrombocytopenia; Varicella Zoster Virus Infection	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543235	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1364		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Celebrex	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543244	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1369			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Herpes Zoster; Ill-Defined Disorder; Malaise; Pain; Rheumatoid Factor Increased; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arthrotec			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543246	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1323		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Aortic Dilatation; Arthralgia; Drug Ineffective; Joint Swelling; Pulmonary Mass	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Kevzara	S	Unknown	Not Reported
	Atorvastatin	C	Unknown	Not Reported
	Vitamin D	C	Unknown	Not Reported
	Candesartan	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543431	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567727			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Amoxicillin Trihydrate;Clavulanate Potassium			C	Unknown			Not Reported
	Amoxil [Amoxicillin]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543593	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201880			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Fatigue; Feeling Abnormal; Therapeutic Response Decreased	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543644	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022646			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Drug Ineffective; Joint Swelling	Orencia			S	Unknown			Bristol Myers Squibb
	Adalimumab			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Amitriptyline			C	Unknown			Not Reported
	Cefazolin			C	Unknown			Not Reported
	Clindamycin			C	Unknown			Not Reported
	Prednisone			C	Unknown	10 Milligram		Not Reported
	Tylenol W/Codeine No. 3			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543729	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1202304		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Infection; Off Label Use; Pharyngeal Oedema; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Arava			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543733	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1202183		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Methotrexate			S	Unknown			Barr
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Neoral			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543737	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1202308		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Response Decreased; Urinary Tract Infection	Methotrexate			S	Subcutaneous	3.5714 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous	2.1429 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	7.1429 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543813	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1202024			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia;	Methotrexate			S	Unknown			Barr
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Actavis
	Diclofenac Potassium			S	Unknown			Actavis
	Sulfamethoxazole W/Trimethoprim			S	Unknown			Teva
	Sulfamethoxazole W/Trimethoprim			S	Unknown			Teva
	Apo-Diclofenac			S	Topical			Not Reported
	Arava			S	Unknown			Not Reported

Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight Decreased	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Gold Sodium Thiomalate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Naprosyn	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Voltaren	S	Unknown	Not Reported
	Tramadol Hydrochloride	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543832	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201901			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatic Enzyme Increased; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Unknown			Barr
	Humira			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544307	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-020899		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Q4wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Leflunomide	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544337	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567702		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544346	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567705			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544394	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567710		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Stomatitis	Rituximab			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tylenol 8 Hr Arthritis Pain			C	Unknown			Not Reported

	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544665	NON-EXPEDITED			US-PFIZER INC-2020112039		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544958	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-MYLANLABS-2020M1026331		31 YR	Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Growth Restriction; Maternal Exposure During Pregnancy; Oligohydramnios; Premature Baby	Calcium Carbonate			S	Unknown	Unk		Not Reported
	Omeprazole			S	Unknown	Unk		Unknown
	Cefotaxime			S	Unknown	Unk		Mylan
	Cefotaxime			S		Unk		Mylan
	Privigen			S	Unknown	Unk		Mylan
	Privigen			S		Unk		Mylan
	Prednisone			S	Unknown	Unk		Mylan
	Methylprednisolone			S	Unknown	Unk		Mylan
	Dexamethasone			S		Unk		Mylan
	Dexamethasone			S	Unknown	Unk		Mylan
	Vitamin B Complex /04259401/			S	Unknown	Unk		Mylan
	Cefixime			S	Unknown	Unk		Mylan
	Metoprolol Tartrate			S	Unknown	Unk		Mylan
	Bisoprolol Fumarate			S	Unknown	Unk		Mylan
	Penicillin G /00000903/			S	Unknown	Unk		Mylan
	Vulmizolin			S	Unknown	Unk		Mylan

Bisulepin	S	Unknown	Unk		Mylan
Ornidazole	S	Unknown	Unk		Mylan
Albumin	S	Unknown	Unk		Mylan
Aminomethylbenzoic Acid	S	Unknown	Unk		Mylan
Magnesium Lactate	S	Unknown	Unk		Mylan
Folic Acid	S	Unknown	Unk		Mylan
Nadroparin Calcium	S	Unknown	Unk		Mylan
Hydroxychloroquine	S	Unknown	Unk		Mylan
Vitamin D /00318501/	S	Unknown	Unk		Mylan
Hydrocortisone	S	Unknown	Unk		Mylan
Etamsylate	S	Unknown	Unk		Mylan
Flebogamma Dif /00025201/	S	Unknown	Unk		Mylan
Fluconazole	S	Unknown	Unk		Mylan
Potassium Chloride	S	Unknown	Unk		Mylan
Paracetamol	S	Unknown	Unk		Mylan
Vitamin K Nos	S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544990	EXPEDITED (15-DAY)		OT	CA-SA-2017SA166761		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort; Adverse Drug Reaction; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Joint Swelling;	Leflunomide			S	Oral	20 Mg,Qd		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	400 Mg,Qd		Sanofi
	Plaquenil			S	Unknown	400 Mg, Qd		Sanofi
	Orencia			S	Subcutaneous	Unk Unk,Unk		Not Reported

Joint Swelling; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Toxicity To Various Agents; Visual Impairment; Visual Impairment	Orencia	S	Intravenous (not otherwise specified)	125 Mg, Qw	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Adalimumab	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
	Actemra	S	Unknown	Unk Unk,Unk	Not Reported
	Methotrexate	C	Subcutaneous	17.5 Mg,Unk	Not Reported
	Methotrexate	C	Subcutaneous	15 Mg,Qw	Not Reported
	Methotrexate	C	Unknown	17 Mg	Not Reported
	Methotrexate	C	Unknown	15 Mg, Qw	Not Reported
	Methotrexate	C	Subcutaneous	25 Mg, Qw	Not Reported
	Methotrexate	C	Subcutaneous	20 Mg, Qw	Not Reported
	Sulfasalazine	C	Oral	1 G,Qd	Not Reported
	Xeljanz	C	Oral	5 Mg,Bid	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Depo-Medrol	C		Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544993	EXPEDITED (15-DAY)		DS, OT	CA-SA-2017SA210576		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Arava			S	Oral	10 Mg,Unk		Sanofi

Leflunomide	S			Sanofi
Leflunomide	S		20 Mg, Qd	Sanofi
Leflunomide	S		10 Mg Qd	Sanofi
Leflunomide	S		Unk	Sanofi
Sodium Aurothiomalate	S	Intramuscular	Unk Unk,Unk	Not Reported
Sodium Aurothiomalate	S	Subcutaneous	Unk	Not Reported
Plaquenil	S		Unk Unk,Unk	Sanofi
Methotrexate	S		20 Mg, Qw, Solution	Not Reported
Methotrexate	S	Unknown	12.5 Df,Unk	Not Reported
Methotrexate	S	Subcutaneous	15 Mg, Qw	Not Reported
Methotrexate	S	Subcutaneous	15 Mg, Qw	Not Reported
Sulfasalazine	S	Unknown	Unk Unk,Unk	Not Reported
Hydroxychloroquine Sulfate	S		200 Mg, Bid	Sanofi
Hydroxychloroquine Sulfate	S		300 Mg	Sanofi
Humira	S	Subcutaneous	40 Mg,Qow	Not Reported
Orencia	S	Subcutaneous	25 Mg	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	250 Mg	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg,Unk	Not Reported
Rituxan	S		Unk	Not Reported
Gold	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous	25 Mg	Not Reported
Enbrel	S		50 Mg	Not Reported
Actemra	S			Not Reported
Actemra	S		Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Q6w	Not Reported
Prednisone	C	Unknown	40 Mg, For 3 Years	Not Reported
Prednisone	C	Unknown	250 Mg, For 7 Months	Not Reported

Bifidobacterium Bifidum	C				Not Reported
Celebrex	C				Not Reported
Loperamide	C				Not Reported
Sulfasalazine	C				Not Reported
Pantoprazole	C				Not Reported
Xeljanz	C	Oral	5 Mg		Not Reported
Simponi	C				Not Reported
Wellbutrin	C				Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C	Oral	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17545125	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2020M1026414			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anaemia; Arthralgia; Fall; Lower Limb Fracture; Occult Blood Positive; Osteoarthritis; Pruritus; Urinary Tract Infection	Methotrexate			S	Unknown	5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	7.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	2.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	2.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	7.5 Mg, Unk		Not Reported
	Mabthera			S	Unknown	500 Mg, Unk		Mylan
	Mabthera			S	Unknown	500 Mg, Unk		Mylan
	Mabthera			S	Unknown	500 Mg, Unk		Mylan
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Mylan
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Mylan
	Rituximab			S	Unknown	500 Mg, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17545370	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020112214			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diarrhoea; Drug Ineffective; Rheumatoid Arthritis	Methotrexate Sodium	S	Unknown	Pfizer
	Xeljanz	S	Unknown	Pfizer
	Arava	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17545594	EXPEDITED (15-DAY)		OT	CA-SA-2019SA130822		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Drug Ineffective; Headache; Joint Swelling; Pain In Jaw; Rheumatoid Arthritis; Therapeutic Response Decreased	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg		Sanofi
	Arava			S		Unk		Sanofi
	Meloxicam			S		15 Mg		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Atorvastatin Calcium			C		20 Mg		Not Reported
	Symbicort			C		Unk		Not Reported
	Gabapentin			C		100 Mg		Not Reported
	Lansoprazole			C		30 Mg		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546119	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1198500			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Haemorrhage	Hydroxychloroquine Sulfate Teva			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546196	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2020111601		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombophlebitis Superficial	Torvast			S				Pfizer
	Paracetamol Alter			S	Oral	1 G, 1x/Day		Not Reported
	Xarelto			S	Oral	20 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546249	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020CA069998		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Oxycodone			S	Unknown	10 Mg		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S				Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulphate			S				Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Minocycline			S				Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown	Unk		Not Reported

Arava	S				Not Reported
Cannabis Sativa	S	Unknown	Unk		Not Reported
Enbrel	S	Subcutaneous	Unk		Not Reported
Enbrel	S				Not Reported
Gold	S	Unknown	Unk		Not Reported
Gold	S				Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Humira	S				Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Orencia	S				Not Reported
Plaquenil	S	Unknown	Unk		Not Reported
Plaquenil	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S				Not Reported
Rituxan	S	Unknown	Unk		Not Reported
Rituxan	S				Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk		Not Reported
Sodium Aurothiomalate	S				Not Reported
Sulfasalazine	S	Unknown	500 Mg		Not Reported
Sulfasalazine	S				Not Reported
Xeljanz	S	Oral	2 Df, Qd		Not Reported
Rituximab	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546340	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3318751-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Prescribed Underdose; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported

Anakinra	S	Unknown	Not Reported
Apo Azathioprine	S	Unknown	Not Reported
Apo Leflunomide	S	Oral	Not Reported
Apo Prednisone	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Azathioprine	S		Not Reported
Celebrex	S	Unknown	Not Reported
Celebrex	S		Not Reported
Celecoxib	S	Unknown	Not Reported
Celecoxib	S		Not Reported
Cimzia	S	Subcutaneous	Not Reported
Etanercept	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Acetaminophen	C		Not Reported
Codeine Phosphate	C		Not Reported
Altace	C		Not Reported
Apo Gabapentin	C	Oral	Not Reported
Atorvastatin Calcium	C		Not Reported
Escitalopram	C		Not Reported
Citalopram Hydrobromide	C		Not Reported
Conjugated Estrogens	C		Not Reported
Cymbalta	C		Not Reported
Escitalopram	C		Not Reported
Estrace	C		Not Reported
Gabapentin	C		Not Reported

Hydrochlorothiazide	C			Not Reported
Hydromorphone Hcl	C			Not Reported
Mupirocin	C	Topical		Not Reported
Pantoprazole	C			Not Reported
Shark Liver Oil	C			Not Reported
Tapentadol Hydrochloride	C			Not Reported
Taro Mupirocin	C	Topical		Not Reported
Tramacet	C	Oral		Not Reported
Tramadol Hydrochloride	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546508	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021288		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546844	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1202539		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Condition Aggravated; Diverticulitis;	Methotrexate			S	Unknown			Barr

H1n1 Influenza; Hepatic Enzyme Increased; Hepatomegaly; Palpitations; Pneumonia; Renal Disorder; Tooth Extraction; Tooth Infection	Chloroquine Diphosphate		S	Unknown	Not Reported
	Belimumab		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546910	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1202524		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Intramuscular			Barr
	Methotrexate			S	Intramuscular			Barr
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Asa			C	Unknown			Not Reported
	Ergocalciferol			C				Not Reported
	Lantus			C				Not Reported
	Lozide			C				Not Reported
	Metformin			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C				Not Reported
	Ramipril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	11624328	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1476711-00		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Synovitis; Tenderness; Tenderness; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Anakinra			C				Not Reported
	Ativan			C				Not Reported
	Benadryl			C				Not Reported
	Cortisone			C	Intramuscular			Not Reported
	Cortisone			C	Intra-arterial			Not Reported
	Dilaudid			C				Not Reported
	Enablex			C				Not Reported
	Lasix			C				Not Reported
	Leflunomide			C				Not Reported
	Loperamide			C				Not Reported
	Norflex			C				Not Reported
	Omnaris			C		Spray, Metered Dose		Not Reported
	Pantoprazole Sodium			C				Not Reported
	Rituxan			C	Intravenous (not otherwise specified)			Not Reported
	Vagifem			C	Vaginal			Not Reported

	Synthroid	C			Not Reported
	Abatacept	C			Not Reported
	Desoximetasone	C	Intra-arterial		Not Reported
	Darifenacin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	12696887	EXPEDITED (15-DAY)		CA, DS, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1453		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Infliximab Hospira			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Remicade	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Infliximab	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Arava	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	12702886	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016087030		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Glucose Increased; Blood Pressure Increased; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Femur Fracture; Gait Disturbance; Gastric Disorder; Glycosylated Haemoglobin Increased; Heart Rate Increased; Hepatic Enzyme	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
	Enbrel			S		Unk		Pfizer
	Enbrel			S	Unknown	50 Milligram, Qd		Pfizer
	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	40milligram, 4 Every 1 Week		Pfizer
	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	40 Milligram, Four Every One Week		Pfizer
	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	50 Milligram, Qd		Pfizer
	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer

Increased; Infection; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphocyte Count Increased; Malaise; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Nausea; Neutrophil Count Increased; Off Label Use; Osteopenia; Pain; Pain In Extremity; Peripheral Swelling; Product Use Issue; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Somnolence; Synovitis; Tooth Abscess; Treatment Failure; Visual Impairment; Weight Decreased; White Blood Cell Count Increased	Enbrel	S	Unknown	Unk	Pfizer
	Enbrel	S	Unknown	50 Milligram, 4 Every 1 Week	Pfizer
	Sulfasalazine	S	Oral	2000 Mg, Unk	Pfizer
	Sulfasalazine	S	Oral	2000 Milligram, Qd	Pfizer
	Sulfasalazine	S	Oral	1000 Milligram, Qd	Pfizer
	Sulfasalazine	S	Oral	2000 Milligram, Unk	Pfizer
	Sulfasalazine	S	Oral	2000 Milligram, Qd	Pfizer
	Sulfasalazine	S	Oral	1000 Milligram, Qd	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	2.5 Mg/Ml, Weekly	Pfizer
	Methotrexate Sodium	S	Subcutaneous	Unk, Weekly (4 Every 1 Week)	Pfizer
	Methotrexate Sodium	S	Unknown	Unk, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	25 Df, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	25 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Subcutaneous	20 Milligram, Qwk	Pfizer
	Arava	S	Oral	20 Mg, 1x/Day	Not Reported
	Arava	S		10 Milligram, Qd	Not Reported
	Arava	S	Unknown	Unk Unk, Qd	Not Reported
	Arava	S	Unknown	10 Milligram, Qd	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Arava	S	Unknown	Unk Unk, Qd	Not Reported
	Plaquenil	S	Unknown	200 Mg, 2x/Day	Not Reported
	Plaquenil	S	Unknown	200 Mg, 2x/Day	Not Reported
	Plaquenil	S		200 Mg, Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
	Plaquenil	S	Unknown	200 Milligram, Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported

Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Unk	Not Reported
Humira	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S		200 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	5 Milligram	Not Reported
Actemra	S	Intravenous (not otherwise specified)	800 Milligram, Q4wk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	200 Milligram, Unk	Not Reported
Orencia	S	Unknown	200 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Q4wk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Subcutaneous	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Tylenol	S	Unknown	Unk	Not Reported
Hydroxychloroquine/Hydroxychlo	S	Oral	200 Milligram, Bid	Not Reported

roquine Sulfate				
Hydroxychloroquine/Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Acetaminophen	S	Unknown	325 Mg, Unk	Not Reported
Acetaminophen	S	Unknown	325 Milligram	Not Reported
Acetaminophen	S	Oral	650 Milligram	Not Reported
Apo-Hydroxyquine	S	Unknown	200 Mg, Bid	Not Reported
Apo-Acetaminophen	S	Unknown	Unk	Not Reported
Apo-Acetaminophen	S	Unknown	Unk	Not Reported
Apo-Prednisone	S		Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Acetaminophen And Codeine Phosphate	S	Unknown	Unk	Not Reported
Apo-Hydro	S		Unk	Not Reported
Apo-Hydro	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
Acetaminophen W/Diphenhydramine Hydrochloride	S	Unknown	Unk	Not Reported
Acetaminophen W/Diphenhydramine Hydrochloride	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	20 Mg, 1x/Day	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Apo Sulfasalazine	S	Unknown	2 G, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Amaryl	S	Unknown	Unk	Not Reported
Otezla	S	Unknown		Not Reported
Stelara	S	Unknown		Not Reported
Meloxicam	C	Unknown	Unk	Not Reported
Meloxicam	C	Unknown	Unk	Not Reported
Tylenol With Codeine No.3	C		Unk, As Needed	Not Reported

Tylenol With Codeine No.3	C		Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Celebrex	C	Oral	200 Mg, 2x/Day	Not Reported
Celebrex	C		200 Milligram, Bid	Not Reported
Hydromorphone Hcl	C		Unk	Not Reported
Methotrexate	C	Unknown	Unk Unk, Weekly	Not Reported
Methotrexate	C	Subcutaneous	25 Milligram, Qwk	Not Reported
Methotrexate	C	Subcutaneous	Unk, 4 Every 1 Week	Not Reported
Methotrexate	C	Unknown	Unk, Qwk	Not Reported
Methotrexate	C	Unknown	25 Dosage Form, Qwk	Not Reported
Methotrexate	C	Subcutaneous	20 Milligram, Qwk	Not Reported
Methotrexate	C	Unknown	Unk	Not Reported
Acetaminophen And Codeine Phosphate	C	Unknown	Unk	Not Reported
Codeine	C	Unknown	Unk	Not Reported
Diphenhydramine	C	Oral	50 Milligram	Not Reported
Glyburide (Micronized)	C	Unknown	Unk	Not Reported
Hydrochlorothiazide	C	Unknown		Not Reported
Lipitor	C	Unknown		Not Reported
Metformin	C	Unknown	Unk Unk, Qd	Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
Percocet [Oxycodone Hydrochloride;Paracetamol]	C	Unknown		Not Reported
Ramipril	C	Unknown		Not Reported
Xeljanz	C	Oral	5 Mg, Bid (2 Every 1 Days)	Not Reported
Xeljanz	C		50 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	12716207	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm Malignant; Onychoclasis; Synovitis; Tooth Loss	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported
	Zostavax			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Apo Hydroxyquine	S	Unknown	Not Reported
Varicella Zoster Vaccine Live	S	Unknown	Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous	Not Reported
Xeljanz	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Xeljanz	C	Unknown	Not Reported
Cortisone	C	Unknown	Not Reported
Cortisone	C	Unknown	Not Reported
Diclofenac	C	Subcutaneous	Not Reported
Desoximetasone	C	Oral	Not Reported
Cortisone Acetate	C	Unknown	Not Reported
Zostavax	C	Unknown	Not Reported
Voltaren	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	12933730	EXPEDITED (15-DAY)		DS, OT	CA-SA-2016SA201530		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical	Arava			S	Oral	10 Mg,Qd		Sanofi
	Sulfasalazine			S	Oral	500 Mg,Bid		Not Reported
	Sulfasalazine			S		1000 Mg, Bid		Not Reported
	Plaquenil			S	Oral	200 Mg,Unk		Sanofi
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Prednisone			S	Unknown	20 Mg,Qd		Not Reported
	Prednisone			S	Unknown	20 Mg,Qd		Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Methotrexate			S		20 Mg		Not Reported

Condition, Insomnia Type	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Hydroxychloroquine	S		Unk	Sanofi
	Methotrexate [Methotrexate Sodium]	S	Subcutaneous	20 Mg,Unk	Not Reported
	Methotrexate [Methotrexate Sodium]	S		Unk	Not Reported
	Actemra	S	Unknown	Unk Unk,Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg,Qw	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
	Orencia	S	Unknown	Unk Unk,Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	2 G,Qcy	Not Reported
	Rituxan	S		2 Unk, Qcy	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	2 G, Q6m	Not Reported
	Etanercept	S		50 Mg, Qw	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	13519996	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038600			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported

Enbrel	S	Unknown	Unk		Not Reported
Fosamax	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	40 Mg, Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Etanercept	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown			Not Reported
Cetirizine	S	Unknown	Unk		Not Reported
Folic Acid	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	13520451	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-039843		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Off Label Use; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Methotrexate Sodium	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Arava	S	Unknown		Not Reported
	Vorhyaluronidase Alfa	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Calcium Carbonate	C	Unknown		Not Reported
	Cymbalta	C	Unknown		Not Reported
	Elavil [Amitriptyline Hydrochloride]	C	Unknown		Not Reported
	Hydrochlorothiazide	C	Unknown		Not Reported
	Imitrex [Sumatriptan]	C	Unknown		Not Reported
	Lyrica	C	Unknown		Not Reported
	Premarin	C	Unknown		Not Reported
	Tenormin	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Sumatriptan	C	Unknown		Not Reported
	Amitriptyline	C	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	13869108	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2444		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Minocycline	S	Unknown	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Plaquenil	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Apo Hydroxyquine	S	Unknown	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Rituximab	S	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	13869342	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2017351180		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity;	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk, Weekly		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Bid		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer

Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Naprosyn	C	Unknown	Unk	Not Reported
	Erythromycin	C		Unk	Not Reported
	Morphine	C	Topical	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	13870276	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2017350057			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Viral Infection	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Pfizer
	Actemra			S	Subcutaneous	162 Mg, Qwk		Not Reported
	Folic Acid			S	Unknown	5 Milligram, Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Apo-Folic Acid			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	400 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported

	Cymbalta		C	Unknown	Unk	Not Reported
	Xeljanz		C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	13921480	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017372781		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk (Prefilled Syringe)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid (1 Every 12 Hours)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

Leflunomide	S	Unknown	Unk		Not Reported
Leflunomide	S	Unknown	Unk		Not Reported
Leflunomide	S	Unknown	Unk		Not Reported
Apo-Leflunomide	S	Unknown	Unk		Not Reported
Imuran	C	Unknown	Unk		Not Reported
Arthrotec	C	Unknown	Unk		Not Reported
Ergocalciferol	C	Unknown	Unk		Not Reported
Ergocalciferol	C	Unknown	Unk		Not Reported
Azathioprine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	14227055	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017506816			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Qwk		Pfizer
	Actemra			S	Subcutaneous	Unk Unk, Qwk		Not Reported
	Arava			S	Unknown	20 Mg, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Meloxicam			S	Oral	7.5 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Mobicox			S	Oral	7.5 Mg, Qd		Not Reported
	Sulfasalazine			C	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	14227318	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017506298		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy;	Enbrel			S	Unknown	50 Mg, Unk		Pfizer

Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate Sodium		S	Subcutaneous	20 Mg, Qwk	Pfizer
	Sulfasalazine		S	Unknown	1000 Mg, Bid	Pfizer
	Hydroxychloroquine Sulfate		S	Unknown	200 Milligram, Bid	Not Reported
	Actemra		S	Unknown	Unk	Not Reported
	Arava		S	Unknown	20 Milligram, Qd	Not Reported
	Arava		S	Oral	20 Milligram, Qd	Not Reported
	Humira		S	Subcutaneous	20 Mg, Qd	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Humira		S	Subcutaneous	20 Mg, Qd	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	200 Mg, Bid	Not Reported
	Prednisone		S	Oral	5 Milligram, Qd	Not Reported
	Xeljanz		C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	14230778	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017510773		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Off Label Use; Product Use Issue; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	15 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Oral	1 G, Qd		Pfizer
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Mg, Qd		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	14570743	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0535		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cystitis; Deformity; Depressed Mood; Encephalitis; Encephalitis Brain Stem; Fibromyalgia; Immunosuppression; Insomnia; Joint Destruction; Loss Of Personal Independence In Daily Activities; Peripheral Swelling; Product Use Issue; Psychiatric Symptom; Rheumatoid Arthritis; Rib Fracture; Seizure; Sepsis; Spinal Deformity	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Celebrex			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Hydromorph Contin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	14632418	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-020711		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Alendronate Sodium			S	Unknown	70 Milligram, Qwk		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Codeine			S	Unknown			Not Reported
	Fosamax			S	Unknown	70 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	25 Mg, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Methotrexate			S	Unknown	12.5 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	10 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	12 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	10 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	12 Mg, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Bid		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown	680 Mg, Qmo		Not Reported
	Tocilizumab			S	Unknown	360 Mg, Qmo		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, Qmo		Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Actemra	S	Unknown	360 Milligram, Qmo	Not Reported
	Actemra	S	Unknown	680 Milligram, Q4wk	Not Reported
	Alendronic Acid	S	Unknown	70 Milligram, Qwk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Ciclosporin	S	Unknown	150 Milligram, Qd	Not Reported
	Xeljanz	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Ciclosporin	C	Unknown	150 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15215485	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018305256		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Qwk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Subcutaneous	162 Mg, 2 Times/Wk		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Q2wk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, 3 Times/Wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Q2wk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, 2x/Week		Not Reported

	Hydroxychloroquine	S	Unknown	400 Unk, Unk (Three In One Week)	Not Reported
	Leflunomide	S		Unk	Not Reported
	Prednisone	C	Unknown	20 Mg, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15246107	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015106204		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Enbrel			S	Subcutaneous	25 Mg, 2x/Week		Pfizer
	Enbrel			S		25 Mg, 2x/Day		Pfizer
	Enbrel			S	Subcutaneous	25 Mg, Cyclic Q2wk		Pfizer
	Enbrel			S		25 Mg, (3 Years, Freq: 2 Week; Interval: 1)		Pfizer
	Enbrel			S		25 Mg, Cyclic Q2wk		Pfizer
	Enbrel			S	Subcutaneous	25 Mg, Unk		Pfizer
	Xeljanz			S		Unk		Pfizer
	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, 1x/Day		Pfizer
	Methotrexate Sodium			S	Vaginal	25 Mg, 4 Times/Wk		Pfizer
	Methotrexate Sodium			S		25 Mg, 4 Times/Wk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, 11 Years, Freq: 1 Week; Interval: 1		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Cyclic Every Two Weeks (Duration Reported As 365 Units Not Reported		Not Reported

Humira	S	Unknown	200 Mg, 2x/Day	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	200 Mg, 2x/Day	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Mg, Monthly, Therapy Duration Reported As 61 (Unit Not Reported), (Freq: 1 Month; Interval: 1)	Not Reported
Orencia	S		Unk, Qd	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	200 Mg, 2x/Day	Not Reported
Plaquenil	S	Unknown	200 Mg, 2x/Day	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Monthly, Therapy Duration Reported As 184 (Unit Not Reported),	Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, 2x/Day	Not Reported
Hydroxychloroquine	S	Unknown	40 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	4 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	40 Mg, Unk	Not Reported

Hydroxychloroquine Sulfate	S	Unknown	200 Mg, 2x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Arava	S	Unknown	20 Mg, Daily	Not Reported
Arava	S		1 Mg, Every 1 Day	Not Reported
Arava	S		20 Mg, Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	1000 Mg, Day 1 &15	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Unk	Not Reported
Cortisone	C	Intramuscular	Unk	Not Reported
Cortisone	C	Intra-articular	Unk	Not Reported
Benadryl	C		Unk, As Needed	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Lasix	C		40 Mg, 3x/Day	Not Reported
Lasix	C	Unknown	Unk	Not Reported
Enablex [Darifenacin Hydrobromide]	C	Unknown	Unk, As Needed	Not Reported
Enablex [Darifenacin Hydrobromide]	C	Unknown	Unk	Not Reported
Ativan	C	Unknown	1 G, Daily At Bedtime	Not Reported
Ativan	C		1 Mg,Every 1 Day	Not Reported
Ativan	C	Unknown	Unk	Not Reported
Loperamide	C		2 Mg, 2x/Day	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown	Unk, 2x/Day	Not Reported
Norflex	C	Unknown	Unk, 2x/Day (Freq: 2 Day; Interval: 1)	Not Reported
Norflex	C		Unk	Not Reported

Omnaris	C	Unknown	Unk (Spray, Metered Dose)	Not Reported
Pantoloc	C	Unknown	Unk	Not Reported
Vagifem	C	Vaginal	Unk	Not Reported
Vagifem	C	Unknown	Unk	Not Reported
Dilaudid	C		4 Mg, Qd	Not Reported
Dilaudid	C	Unknown	4 Mg, Every 6 Hours	Not Reported
Dilaudid	C		4 Mg, Unk	Not Reported
Dilaudid	C	Unknown	Unk	Not Reported
Abatacept	C		Unk	Not Reported
Leflunomide	C		Unk	Not Reported
Kineret	C	Unknown	100 Mg, Unk	Not Reported
Anakinra	C	Unknown	100 Mg, Unk	Not Reported
Anakinra	C		100 Mg, Unk	Not Reported
Furosemide	C	Unknown	40 Mg, Three Every One Day	Not Reported
Furosemide	C	Unknown	40 Mg, 3x/Week	Not Reported
Furosemide	C	Unknown	Unk	Not Reported
Darifenacin Hydrobromide	C	Unknown	Unk (Freq: As Needed)	Not Reported
Darifenacin Hydrobromide	C	Unknown	Unk	Not Reported
Desoximetasone	C	Oral	Unk	Not Reported
Desoximetasone	C	Intramuscular	Unk	Not Reported
Desoximetasone	C	Unknown	Unk	Not Reported
Desoximetasone	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Codeine	C	Unknown	Unk	Not Reported
Hydromorphone	C	Unknown	Unk	Not Reported
Kadian	C	Unknown	Unk	Not Reported
Oxyneo	C	Unknown	Unk	Not Reported
Restasis	C	Unknown	Unk	Not Reported

Trimethoprim	C	Unknown	Unk	Not Reported
Urispas	C	Unknown	200 Mg, Unk	Not Reported
Morphine Sulfate	C	Unknown	Unk	Not Reported
Diphenhydramine	C	Unknown	Unk	Not Reported
Diphenhydramine	C	Unknown	Unk	Not Reported
Dexamethasone	C	Unknown	Unk	Not Reported
Dexamethasone	C	Oral	Unk	Not Reported
Darifenacin	C	Unknown	Unk	Not Reported
Dyclone	C	Unknown	Unk	Not Reported
Kenalog	C	Intra-articular	40 Mg, Unk	Not Reported
Kenalog	C	Unknown	40 Milligram	Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	C		Unk Unk, As Necessary (Freq: As Needed)	Not Reported
Plantago Ovata	C	Unknown	Unk	Not Reported
Dyclonine Hydrochloride	C		Unk	Not Reported
Orphenadrine [Orphenadrine Hydrochloride]	C	Unknown	1 Dosage Form, Bid	Not Reported
Pantoprazole Sodium	C		Unk	Not Reported
Pantoprazole	C		Unk	Not Reported
Triamcinolone Acetonide	C	Intra-articular	40 Milligram, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15357865	EXPEDITED (15-DAY)		HO	PHHY2018DK086994		47 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia Mycoplasmal	Azathioprine			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Insulin			C	Unknown	Unk (On Pump)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15383851	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-082919			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Injection Site Reaction; Intentional Product Use Issue; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Dispensing Error; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Decreased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Treatment	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	15 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	200 Milligram, Qmo		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	200 Milligram, Qwk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram/Sq. Meter, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	Unk Unk, Qwk		Not Reported
	Hydroxychloroquine Phosphate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	420 Milligram		Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

Failure; Vascular Access Complication; White Blood Cell Count Increased	Adalimumab		S	Subcutaneous	40 Milligram, Qwk	Not Reported
	Adalimumab		S	Unknown		Not Reported
	Etanercept		S	Subcutaneous	15 Milligram, Q2wk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15617576	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555631-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Chest Pain; Eye Ulcer; Foot Deformity; Hand Deformity; Headache; Ill-Defined Disorder; Injection Site Reaction	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Leflunomide			C				Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15619140	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555653-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Swelling	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported

	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15619319	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2554744-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Gastrointestinal Toxicity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lipitor			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15619584	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2555197-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cerebrovascular Accident; Contraindicated Product Administered; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Joint Swelling; Rheumatoid Arthritis; Wheelchair User	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Leflunomide Apotex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Aspirin	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15620413	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2555889-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Limb Deformity; Loose Body In Joint; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15621393	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557319-00		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15627588	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2559128-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Infection; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Pain; Synovitis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported
	Plaquenil			S	Oral			Not Reported

Naproxen Sodium	S	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Risedronate	C	Oral	Not Reported
Arava	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15660935	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016545757		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Tolerance Decreased; Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		50 Mg, Weekly		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Leflunomide			S	Oral			Not Reported
	Plaquenil			S		4 Years		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported
	Prednisone			C		10 Mg, 1x/Day		Not Reported
	Coversyl [Perindopril Erbumine]			C		Unk		Not Reported
	Hydroxychloroquine			C				Not Reported
	Cephalexine			C	Unknown	500 Milligram, Qid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15710031	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015280551		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Nodule; Rheumatoid Arthritis	Enbrel	S	Subcutaneous	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15720388	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017364037		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Joint Swelling; Malaise; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Sleep Disorder	Enbrel			S	Unknown	50 Milligram		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Etanercept			S	Unknown	Unk		Pfizer
	Tofacitinib Citrate			S	Oral	5 Mg, Bid		Pfizer
	Minocin			S	Unknown	Unk		Pfizer
	Minocycline Hcl			S	Unknown	Unk		Pfizer
	Salazopyrin			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	15 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Sodium Aurothiomalate	S	Subcutaneous	Unk	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Ustekinumab	S	Unknown	Unk	Not Reported
Ustekinumab	S	Subcutaneous	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Myochrysine	S	Parenteral	Unk	Not Reported
Myochrysine	S	Subcutaneous	Unk	Not Reported
Myochrysine	S	Unknown	Unk	Not Reported
Myochrysine	S	Intramuscular	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous drip	Unk	Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported

	Orencia			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Prednisone			C		Unk			Not Reported
	Abatacept			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15781901	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017013508		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S		25 Mg, 2x/Week		Pfizer
	Enbrel			S	Unknown	25 Mg, Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Apo-Leflunomide			S	Oral	20 Mg, Daily		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported
	Humira			S	Subcutaneous	40 Mg, Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Unknown	300 Mg, Every 6 Weeks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, 1 Every 6 Weeks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S		200 Mg, 2x/Day		Not Reported
	Orencia			S		Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

	Rituxan	S		Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Apo-Hydroxyquine	S		200 Mg, Bid	Not Reported
	Hydroxychloroquine Sulfate	S		200 Mg, 2x/Day	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	1 Gram	Not Reported
	Wellbutrin	C	Unknown	Unk	Not Reported
	Sulfasalazine	C		1 G, 2x/Day	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15926889	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2651972-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous	Tablet		Not Reported

Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Neoral	S	Subcutaneous	Not Reported
Neoral	S	Oral	Not Reported
Orencia	S	Subcutaneous	Not Reported
Plaquenil	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz Xr	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15953507	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-012131		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Off Label Use; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)		
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Aspirin [Acetylsalicylic Acid]	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Prednisone	C	Unknown	5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15995703	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2674768-00		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Vaginal	Dosage Form Solution		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

	Ativan	C	Unknown		Not Reported
	Dilaudid	C	Unknown		Not Reported
	Diphenhydramine	C			Not Reported
	Enablex	C	Unknown		Not Reported
	Lasix	C	Unknown		Not Reported
	Loperamide	C			Not Reported
	Norflex	C	Unknown		Not Reported
	Omnaris	C	Unknown	Spray, Metered Dose	Not Reported
	Pantoprazole Sodium Anhydrous	C			Not Reported
	Synthroid	C	Unknown		Not Reported
	Vagifem	C	Unknown		Not Reported
	Pantoloc	C		(Enteric Coated)	Not Reported
	Darifenacin Hydrobromide	C			Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Benadryl	C	Unknown		Not Reported
	Plantago Ovata	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16075583	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-012946		14 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Hair Follicle Tumour Benign; Intentional Product Use Issue; Lymphoproliferative Disorder; Off Label Use; Off Label Use Of Device; Product Use In Unapproved Indication; Renal Cell Carcinoma	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Amlodipine Tablets			S	Unknown	Unk		Aurobindo
	Metformin Tablet			S	Unknown	Unk		Aurobindo
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S				Not Reported
	Azathioprine			S				Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Enalapril Maleate			S	Unknown	Unk		Not Reported
	Ferrous Fumarate			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	100.0 Milligram, 1 Every 1		Not Reported

			Month	
Infliximab	S	Unknown	1000.0 Milligram, 1 Every 1 Month	Not Reported
Infliximab	S			Not Reported
Insulin	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S			Not Reported
Methotrexate	S			Not Reported
Nutropin	S	Subcutaneous	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Ranitidine	S	Unknown	Unk	Not Reported
Sulfamethoxazole	S	Unknown	Unk	Not Reported
Androderm	S	Unknown	Unk	Not Reported
Protropin	S	Intramuscular	Unk	Not Reported
Acetazolamide	S	Unknown	Unk	Not Reported
Calcium Carbonate	S	Unknown	Unk	Not Reported
Cyclosporine	S	Unknown	Unk	Not Reported
Cyclosporine	S			Not Reported
Ferric Hydroxide Polymaltose Complex	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S			Not Reported
Insulin Human	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16332181	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019210438			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hyperhidrosis; Inappropriate Schedule Of Product Administration;	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer

Nausea; Rheumatoid Arthritis	Estradot	S	Transdermal	Unk, Weekly		Not Reported
	Hydroxychloroquine Sulfate	S		Unk		Not Reported
	Leflunomide	S	Unknown	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16334554	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018103158		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Product Use Issue; Treatment Failure; Uveitis	Enbrel			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, Bid		Pfizer
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	10 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram		Pfizer
	Tofacitinib Citrate			S	Unknown	Unk		Pfizer
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, (1 Every 2 Week(S))		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Leflunomide	S	Unknown	Unk		Not Reported
Sarilumab	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	40 Milligram		Not Reported
Apo-Leflunomide	S	Unknown	Unk		Not Reported
Tocilizumab	S	Unknown	Unk		Not Reported
Rabeprazole Sodium	C	Oral	20 Mg, Qd		Not Reported
Prednisone	C		10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16343860	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019217974			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer
	Sulfasalazine			S	Unknown	2 Gram, Qd		Pfizer
	Actemra			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16387751	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-050993		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Rituximab			S	Intravenous drip			Not Reported

Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Actemra	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, 2 Times/Wk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Unknown	200 Milligram, Bid	Not Reported
	Humira	S	Unknown	1 Every 2 Weeks	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	4 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
	Vagifem	C	Vaginal		Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Qmo	Not Reported
	Arava	S	Unknown	20 Milligram, Qd	Not Reported
	Ativan	C	Unknown	1 Gram	Not Reported
	Darifenacin	C	Unknown		Not Reported
	Desoximetasone	C	Oral		Not Reported
	Dilaudid	C	Unknown	4 Milligram	Not Reported
	Diphenhydramine Hydrochloride	C	Unknown		Not Reported
	Furosemide	C	Unknown	40 Milligram, 3 Times/Wk	Not Reported
	Loperamide	C	Unknown	Unk, Bid	Not Reported
	Norflex [Orphenadrine Citrate]	C	Unknown	Unk, Bid	Not Reported
	Omnaris	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Anakinra	C	Unknown	100 Milligram	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk	Not Reported

	Codeine	C	Unknown	Unk	Not Reported
	Darifenacin Hydrobromide	C	Unknown	Unk	Not Reported
	Hydromorphone	C	Unknown	Unk	Not Reported
	Kadian	C	Unknown	Unk	Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Intra-articular	40 Milligram	Not Reported
	Lasix [Furosemide]	C	Unknown	Unk	Not Reported
	Morphine Sulfate	C	Unknown	Unk	Not Reported
	Oxyneo	C	Unknown	Unk	Not Reported
	Pantoloc [Pantoprazole]	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Restasis	C	Unknown	Unk	Not Reported
	Rituxan	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Trimethoprim	C	Unknown	Unk	Not Reported
	Urispas	C	Unknown	200 Milligram	Not Reported
	Leflunomide	C	Unknown		Not Reported
	Desoximetasone	C	Intramuscular		Not Reported
	Desoximetasone	C	Intra-arterial		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16600726	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-068199		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Deformity; Infusion Related Reaction; Joint Swelling; Off Label Use; Pain; Pemphigus; Rash; Rheumatoid Factor Positive; Swelling; Systemic Lupus Erythematosus; Wound	Cetirizine	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown	50 Milligram	Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk Unk, Qd	Not Reported
	Prednisone	S	Unknown		Not Reported
	Desoximetasone	S	Cutaneous		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Hydrocortisone Acetate	S	Cutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Urethral	400 Milligram, Qd	Not Reported
	Leflunomide	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16691316	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2885135-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16802106	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019396164		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Enbrel			S		50 Mg, Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S		Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

Ergocalciferol	C		Unk, Weekly		Not Reported
Dorzolamide Hydrochloride And Timolol Maleate	C		Unk, 2x/Day		Not Reported
Estrogel	C		0.6 %, 3x/Day		Not Reported
Furosemide	C		40 Mg, 1x/Day		Not Reported
Morphine	C	Unknown	Unk		Not Reported
Potassium Chloride	C	Unknown	1500 Mg, 1x/Day		Not Reported
Valsartan	C		320 Mg, 1x/Day		Not Reported
Xalatan	C		50 Ug, 1x/Day		Not Reported
Zingiber Officinale	C	Oral	500 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16817883	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019399548			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, 1x/Day		Pfizer
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	50 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported
	Orencia			S	Unknown	750 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Gold			S	Unknown	50 Milligram		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16830577	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-27321			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Contraindicated Product Administered; Drug Intolerance; Headache; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Vomiting	Infliximab			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Morphine			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17033629	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019493322			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Pantoprazole			S	Unknown	Unk		Pfizer
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Infliximab Hospira			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Morphine Sulfate			S	Unknown	Unk		Pfizer
	Morphine Hydrochloride			S	Unknown	Unk		Not Reported
	Cefixime			S	Unknown	Unk		Not Reported
	Imuran [Azathioprine]			S	Oral	100 Milligram		Not Reported
	Nifedipine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rivotril			S	Unknown	Unk		Not Reported

	Zantac	S	Unknown	Unk		Not Reported
	Zopiclone	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17215587	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-39411		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Cosentyx			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Otezla			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Simponi			S	Unknown	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Calcium			C	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown	Unknown		Not Reported

Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown	Unknown	Not Reported
Ergocalciferol	C	Unknown	Unknown	Not Reported
Ergocalciferol	C	Unknown	Unknown	Not Reported
Estradiol	C	Unknown	Unknown	Not Reported
Estradiol	C	Unknown		Not Reported
Furosemide	C	Unknown		Not Reported
Gravol Ginger	C	Unknown		Not Reported
Morphine	C	Unknown	Unknown	Not Reported
Potassium Chloride	C	Unknown		Not Reported
Valsartan	C	Unknown		Not Reported
Xalatan	C	Unknown		Not Reported
Xalatan	C	Ophthalmic	Solution Ophthalmic	Not Reported
Xeljanz	C	Oral		Not Reported
Zingiber Officinale	C	Oral		Not Reported
Estrogel	C	Unknown		Not Reported
Estrogel	C	Unknown		Not Reported
Baclofen	C	Unknown		Not Reported
Gravol	C	Unknown	Unknown	Not Reported
Gravol Ginger Nighttime	C	Unknown	Unknown	Not Reported
Levaquin	C	Unknown		Not Reported
Tofacitinib Citrate	C	Oral		Not Reported
Acetaminophen	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17283605	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP005143		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Doxycycline			S	Unknown	50 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex

Leflunomide	S	Unknown	Unk	Apotex
Prednisone	S	Oral	5 Mg, Bid	Not Reported
Prednisone	S	Oral	5 Mg, Unk	Not Reported
Enbrel	S	Unknown	50 Mg, Q.Wk.	Not Reported
Orencia	S	Intravenous (not otherwise specified)	500 Mg, Unk (Once In 4 Weeks)	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Xeljanz	S	Unknown	5 Mg, Unk	Not Reported
Methotrexate	S	Oral	25 Mg, Q.Wk.	Not Reported
Methotrexate	S	Oral	Unk Unk, Q.Wk.	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Folic Acid	C	Unknown	5 Mg, Unk	Not Reported
Naproxen	C	Unknown	500 Mg, Bid	Not Reported
Simponi	C	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17390882	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018169790		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use	Enbrel			S		50 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Enbrel			S		50 Mg, 1x/Day		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

Ciclosporin	S		Unk	Not Reported
Leflunomide	S		Unk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		Unk	Not Reported
Apo-Hydroxyquine	S		Unk	Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Leflunomide	S		Unk	Not Reported
Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported
Methotrexate Sodium	C		25 Mg, Weekly	Not Reported
Hydroxychloroquine	C		200 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17422939	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-010154		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every One Week		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every		Not Reported

				One Day	
	Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Remicade	S	Unknown	300 Milligram, Q6wk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Wellbutrin	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17440627	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2016346047		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Chest Pain; Contraindicated Product Administered; Discomfort; Drug Hypersensitivity; Drug Ineffective; Duodenal Ulcer Perforation; Dyspnoea; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapy	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Milligram (1 Every 24 Hours)		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Sulfasalazine			S	Oral	500 Milligram		Pfizer
	Sulfasalazine			S	Oral	1000 Milligram, Bid		Pfizer
	Sulfasalazine			S		1 Gram, Bid		Pfizer
	Tofacitinib Citrate			S	Unknown	5 Milligram, Bid		Pfizer
	Tofacitinib Citrate			S	Unknown	5 Milligram, Bid		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	400 Milligram, Qd		Not Reported
	Arava			S		Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported

Non-Responder; Treatment Failure; Wound	Cimzia	S		Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Orencia	S		Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Atasol [Paracetamol]	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Diclofenac	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S		Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfathalidine	S	Oral	500 Milligram	Not Reported

Sulfathalidine	S	Oral	1000 Milligram, Bid		Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk		Not Reported
Fosamax	S	Oral	Unk		Not Reported
Fosamax	S	Oral	Unk		Not Reported
Apo-Prednisone	S	Unknown	Unk		Not Reported
Vitamin C	C		Unk		Not Reported
Vitamin D	C		Unk		Not Reported
Alaskan Salmon Oil	C		Unk		Not Reported
Glucosamine	C		Unk		Not Reported
Lansoprazole	C		30 Mg, 2x/Day		Not Reported
Ativan	C		2 Mg, 3x/Day, As Needed		Not Reported
Salazopyrin	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17547396	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-059951			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Cefixime			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Unknown	Unk		Aurobindo
	Bisoprolol			S	Unknown	Unk		Not Reported
	Imuran			S	Oral	100 Milligram		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Morphine			S	Unknown	Unk		Not Reported
	Nifedipine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

	Rivotril	S	Unknown	Unk		Not Reported
	Zantac	S	Unknown	Unk		Not Reported
	Zopiclone	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17547515	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568992			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17547563	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201804-001263			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pneumonia	Hydroxychloroquine			S	Unknown	Unk, Tablet		Concordia
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

Salazopyrin	S	Unknown	Unk		Not Reported
Leflunomide	S	Oral	Unk		Not Reported
Leflunomide	S	Unknown	Unk		Not Reported
Xeljanz	C		Unk		Not Reported
Pantoprazole	C				Not Reported
Methotrexate	C		Unk		Not Reported
Loperamide	C		Unk		Not Reported
Celebrex	C		Unk		Not Reported
Bifidobacterium Bifidum	C		Unk		Not Reported
Align	C		Unk		Not Reported
Actemra	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17547565	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201804-001261			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Leflunomide			S	Oral	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Bifidobacterium Bifidum			C		Unk		Not Reported
	Loperamide			C		Unk		Not Reported
	Pantoprazole			C				Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17547716	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201805-001646			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk, Tablet		Concordia
	Silver			S	Oral	Unk		Not Reported
	Sulfadiazine			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Penicillin G Sodium			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported
	Desoximetasone			C		Unk		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported
	Tofacitinib Citrate			C		Unk		Not Reported
	Tylenol [Paracetamol]			C		Unk		Not Reported
	Cortisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17547762	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201804-001274			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung	Hydroxychloroquine			S	Oral	Unk		Concordia
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia
	Erythromycin			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk, Subcutaneous Solution		Not Reported

Disease; Malaise; Mass Excision; Nodule; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Methotrexate	S	Oral	22.5 Mg, Weekly	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Novo-Rythro	S	Unknown	Unk	Not Reported
	Risedronate Sodium	S	Oral	35 Mg, Weekly	Not Reported
	Marijuana	C		Unk	Not Reported
	Wellbutrin	C		Unk	Not Reported
	Celebrex	C		Unk	Not Reported
	Ergocalciferol	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548082	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023061		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Hand Deformity; Headache; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qd		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548119	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1391			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548364	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568773			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548412	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568775			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Methotrexate	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Remicade	S	Unknown		Not Reported
Simponi	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548444	EXPEDITED (15-DAY)		OT	NVSC2020CA073084		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Oral	Unk		Novartis
	Cyclosporine			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	1 Df, Qw		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg		Not Reported
	Rituxan			S	Unknown			Not Reported

	Sulfasalazine		S	Oral	Unk	Not Reported
	Xeljanz		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548451	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567814		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Rituxan			S	Intravenous drip			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548465	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203461			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Kevzara			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Acetaminophen			C	Unknown	1300 Milligram Daily;		Not Reported
	Atacand			C	Unknown			Not Reported

	Folic Acid	C	Unknown		Not Reported
	Hydrodiuril	C	Unknown		Not Reported
	Kevzara	C	Unknown		Not Reported
	Neurontin	C	Unknown	1800 Milligram Daily;	Not Reported
	Premarin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548476	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203253			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Fatigue; Joint Swelling; Leukopenia; Nausea; Pain In Extremity; Peripheral Swelling; Vomiting; Weight Decreased	Methotrexate			S	Unknown	2.8571 Milligram Daily;		Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Calcium			C				Not Reported
	Fentanyl			C				Not Reported
	Folic Acid			C				Not Reported
	Magnesium			C				Not Reported
	Naproxen Sodium			C				Not Reported
	Pantoprazole			C				Not Reported
	Potassium			C				Not Reported
	Tramadol			C				Not Reported
	Vitamin D[Colecalciferol]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548477	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203601		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma;	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Synovitis	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Xalatan	S		50 Microgram Daily;	Not Reported
	Actemra	S	Unknown		Not Reported
	Dorzolamidehydrochloride/Timolol Maleate	C			Not Reported
	Ergocalciferol	C			Not Reported
	Estrogel	C		1.8 Percent Daily;	Not Reported
	Furosemide	C		40 Milligram Daily;	Not Reported
	Morphine	C			Not Reported
	Potassium Chloride	C		1500 Milligram Daily;	Not Reported
	Valsartan	C		320 Milligram Daily;	Not Reported
	Zingiber Officinale	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548478	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203488			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Reactine [Cetirizine]			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Topicort	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548712	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203265			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Treatment Failure	Methotrexate			S	Unknown			Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Tylenol Arthritis Pain 8h			C				Not Reported
	Desoximetasone			C		20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548859	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203616		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Headache; Migraine; Off Label Use; Product Use Issue; Respiratory Tract Infection; Therapeutic Product Effect Incomplete; Urinary Tract Infection;	Methotrexate			S	Subcutaneous			Barr
	Anakinra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Arava			S	Unknown	10 Milligram Daily;		Not Reported

White Blood Cell Count Decreased	Arava		S	Unknown	10 Milligram Daily;	Not Reported
	Meloxicam		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548868	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203538			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Otezla			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17549106	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204060		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Mass; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Prednisone			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17549539	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020AMR042663			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Product Use Issue; Toxicity To Various Agents	Benlysta			S		Unk		Glaxosmithkline
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17549774	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2020-012083		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Reconstitution Inflammatory Syndrome; Neutrophilia; Whipple'S Disease	Methylprednisolone			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cyclobenzaprine			C	Unknown	Unk		Not Reported
	Celecoxib			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17550494	NON-EXPEDITED			NVSC2020US075268		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17550624	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021775			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diarrhoea; Drug Ineffective; Drug-Induced Liver Injury; Headache	Orencia		S	Subcutaneous	125 Milligram, Qwk	Bristol Myers Squibb
	Azathioprine		S	Unknown	150 Milligram, Qd	Not Reported
	Cimzia		S	Subcutaneous	200 Milligram, Q2wk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Methotrexate		C	Subcutaneous	15 Milligram, Qwk	Not Reported
	Sulfasalazine		C	Unknown	500 Milligram, Q12h	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17550986	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-08585		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Ciclosporin			S	Oral	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous, Single-Use Pre-Filled Syringe		Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Solution, Subcutaneous		Not Reported

	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Lyrica	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Rituximab	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Simponi	S	Unknown	Unknown, Solution, Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Prednisone	C	Unknown	Unknown	Not Reported
	Piroxicam	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17551371	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021283			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Neutropenia; White Blood Cell Count Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17551480	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023095		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17551711	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021350		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			C	Unknown	0.8 Milliliter		Not Reported

	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552311	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021309		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552323	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204244		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Oropharyngeal Pain; Pain; Pulmonary Embolism; Swelling; Upper-Airway	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Cough Syndrome	Anakinra	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Warfarin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552337	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1204372		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Circumstance Or Information Capable Of Leading To Medication Error; Condition Aggravated; Intervertebral Discitis; Pyrexia; Synovitis; Transaminases Increased	Methotrexate			S	Unknown			Barr
	Apo-Prednisone			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552354	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203747			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Mycophenolate Mofetil			S	Unknown			Teva
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552356	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204264			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Methotrexate	S	Unknown	20 Milligram Daily;		Barr
	Actemra	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S	Unknown			Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Meloxicam	C	Unknown			Not Reported
	Sulfasalazine	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552357	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204242		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Cough; Drug Ineffective; Headache; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Viral Infection	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552382	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1204376		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Hypertensive Heart Disease; Peripheral Swelling; Therapeutic Response Changed	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Oral			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552406	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3324326-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Epicondylitis; Malaise; Musculoskeletal Pain; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Haemophilus Influenzae			C		Vaccine		Not Reported
	Prevnar 13			C	Intramuscular			Not Reported
	Tetanus Vaccine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552708	EXPEDITED (15-DAY)		OT	NVSC2020CA073106		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Cyclosporine			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported

Methotrexate	S	Subcutaneous	20 Mg	Not Reported
Methotrexate	S	Oral	20 Mg	Not Reported
Methotrexate	S	Oral	20 Mg	Not Reported
Methotrexate	S	Subcutaneous	20 Mg	Not Reported
Methotrexate	S	Oral	20 Mg	Not Reported
Methotrexate	S	Oral	20 Mg	Not Reported
Methotrexate	S	Oral	20 Mg	Not Reported
Methotrexate	S	Subcutaneous	20 Mg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
Humira	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Orencia	S	Subcutaneous	125 Mg	Not Reported
Orencia	S	Subcutaneous	125 Mg	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg	Not Reported
Rituxan	S	Unknown	Unk	Not Reported

	Sulfasalazine	S	Oral	Unk		Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552911	EXPEDITED (15-DAY)		OT	NVSC2020CA071955		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral			S	Unknown	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8.0 Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Remicade			S	Unknown	3 Mg		Not Reported
	Sulphasalazine			S	Oral	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17553141	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1027175			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Disease Recurrence; Drug Ineffective	Prednisone	S	Unk	Not Reported
	Hydroxychloroquine	S	200 Milligram, Qd For 3 Months	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	13816053	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017329621		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	1 Dosage Form, Qwk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Prednisone			C	Oral	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Arava			C		Unk		Not Reported
	Codeine			C	Unknown	Unk		Not Reported
	Tylenol [Paracetamol]			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Lyrica	C	Oral	Unk		Not Reported
Lyrica	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	13856372	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070330			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Off Label Use; Rash; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qd		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	13929661	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2691		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Therapeutic Product Effect Decreased; Weight Decreased	Plaquenil	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	14447073	EXPEDITED (15-DAY)		OT	CA-SA-2017SA043369		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Arthropathy; Condition Aggravated; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Finger Deformity; Limb Operation; Off Label Use; Pain; Peripheral Swelling; Peripheral Swelling; Rash; Swelling; Tendon Disorder; Tendon Operation; Tenosynovitis; Treatment Failure; Urticaria; Urticaria; Wrist Surgery	Arava			S	Oral	Unk		Sanofi
	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rocuronium Bromide			S	Unknown	Unk Unk,Unk		Not Reported
	Rocuronium Bromide			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk Unk,Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Benzylpenicillin Sodium			S	Unknown	Unk Unk, Unk		Not Reported
	Phenoxymethylpenicillin Potassium			S	Unknown	Unk		Not Reported
	Sulfamethoxazole/Trimethoprim			S	Unknown	Unk Unk, Unk		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported

	Humira	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Gold	S	Unknown	Unk Unk, Unk	Not Reported
	Rituximab	S		Unk	Not Reported
	Prednisone	C	Unknown	Unk Unk,Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	14570820	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0542		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Elbow Deformity; Headache; Hepatic Enzyme Increased; Liver Function Test Increased; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	14630900	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2018AP007493		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Pregnancy; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Apo-Prednisone	S	Unknown	Unk	Apotex
	Cetirizine	S	Unknown	10 Mg, Unk	Apotex
	Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Qd	Apotex
	Hydroxychloroquine	S	Oral	Unk	Apotex
	Prednisone	S	Oral	Unk (Therapy Duration 365 Unit Unspecified)	Apotex
	Apo-Hydroxyquine	S	Unknown	Unk	Apotex
	Leflunomide	S	Oral	Unk	Apotex
	Diclofenac Sodium	S	Unknown	Unk	Apotex
	Apo-Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Mg, Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Methotrexate	S	Oral	25 Mg, Unk	Not Reported
	Methotrexate	S	Oral	20 Mg, Qd	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk (Therapy Duration 365 Unit Unspecified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk (Therapy Duration: 365 Unspecified Unit)	Not Reported

	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Oral	1000 Mg, Bid (Therapy Duration 365 Unit Unspecified)	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	10 Mg, Unk	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Unk	Not Reported
	Cortisone	S	Oral	Unk	Not Reported
	Plaquenil /00072602/	S	Oral	400 Mg, Qd	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Sulfathalidine	S	Unknown	Unk	Not Reported
	Tofacitinib Citrate	S	Unknown	5 Mg, Bid	Not Reported
	Topicort /00028604/	S	Cutaneous	Unk	Not Reported
	Salazopyrin	C	Unknown	Unk	Not Reported
	Atasol /00020001/	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	14634899	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0737		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Tremor	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Sulfasalazine	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Cimzia	S	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Pantoprazole Magnesium	C	Unknown	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Zopiclone	C	Unknown	Not Reported
Pantoprazol Sodium	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Tenofovir	C	Unknown	Not Reported
Pantoprazol	C	Unknown	Not Reported
Tenofovir Disoproxil	C	Unknown	Not Reported
Pantoprazole Sodium	C	Unknown	Not Reported
Pantoprazole Bluefish	C	Unknown	Not Reported

	Pantoprazole		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	14788664	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1170			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	14836032	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1328		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown	2x/Week		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Plaquenil	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15242994	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1069		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Product Use Issue; Rash; Skin Mass; Therapy Non-Responder	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Subcutaneous	Not Reported
	Apo-Hydroxyquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Prednisone	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Prednisone Acetate	S	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15243408	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0441		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Pneumonia;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Skin Reaction; Synovitis; Thyroid Disorder; Thyroxine Decreased; Treatment Failure; Vomiting	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Otezla	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Methadone	S	Unknown	Not Reported
	Ramipril	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Estrogel	C	Unknown	Not Reported
	Calcium	C	Unknown	Not Reported
	Xalatan	C	Unknown	Not Reported
	Cosopt	C	Unknown	Not Reported
	Furosemide	C	Unknown	Not Reported
	Valsartan	C	Unknown	Not Reported
	Vitamin D	C	Unknown	Not Reported
	Jampk20	C	Unknown	Not Reported
	Dorzolamide Hcl/Timolol Maleate	C	Unknown	Not Reported
	Baclofen	C	Unknown	Not Reported
	Levaquin	C	Unknown	Not Reported
	Potassium Chloride	C	Unknown	Not Reported

	Zingiber Officinale	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Cortisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Estradiol	C	Unknown	Not Reported
	Morphine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15293692	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1469		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15621032	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557288-00		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Photosensitivity Reaction; Stomatitis; Urticaria	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Oxycodone			S	Unknown	Cr Tablet		Not Reported
	Enbrel			S	Unknown			Not Reported
	Marijuana			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Oxycodone Hydrochloride			S	Unknown			Not Reported
	Cannabis Sativa			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actemra			C				Not Reported
	Enbrel			C				Not Reported
	Leflunomide			C				Not Reported
	Lyrica			C	Oral			Not Reported
	Oxycodone			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15622638	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2557282-00		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disability; Drug Ineffective; Dyspnoea; Impaired Work	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Rash; Skin Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Plaquenil	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Tofacitinib Citrate	S	Oral		Not Reported
	Prednisone Acetate	S	Unknown		Not Reported
	Ergocalciferol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15622672	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557461-00		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Rheumatoid Arthritis	Humira	S	Subcutaneous		Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	Single-Use	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Plaquenil	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15622680	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557508-00		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Musculoskeletal Disorder; Skin Warm	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15624172	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556726-00		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Cyst; Bone Erosion; Drug Ineffective; Hypertension; Therapeutic Response Decreased	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15721414	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1025		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Loss Of Personal Independence In Daily Activities; Nodule; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15855189	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017546580		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Incorrect Route Of Product Administration; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	50 Mg, 2x/Day		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Tofacitinib Citrate			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Pfizer
	Kevzara			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Every 10 Days		Not Reported

Humira	S	Subcutaneous	40 Milligram, Q (Every)14 Day	Not Reported
Humira	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Unknown	40 Mg, Unk	Not Reported
Humira	S	Unknown	40 Mg, Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	50 Milligram, Q4wk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
Rituxan	S	Subcutaneous	Unk	Not Reported
Cimzia	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Abatacept	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S		Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	200 Milligram, Bid	Not Reported
Adalimumab	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Adalimumab	S	Unknown	40 Milligram, 1 Every 14 Days	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	750 Milligram, Q4wk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not	1 Gram	Not Reported

					otherwise specified)					
	Rabeprazole Sodium			C	Oral	20 Mg, 1x/Day				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16075451	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-012895		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Alendronic Acid Tablets			S	Unknown	70 Milligram, 1 Every 1 Week(S)		Aurobindo
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, 1 Every 2 Week(S)		Not Reported
	Humira			S	Unknown	40 Milligram, 1 Every 1 Week(S)		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	10 Milligram, 1 Every 1 Week(S)		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram, 1 Every 1 Week(S)		Not Reported
	Methotrexate			S	Unknown	10 Milligram, 1 Every 1 Week(S)		Not Reported
	Methotrexate			S	Unknown	12 Milligram		Not Reported
	Methotrexate			S	Oral	10 Milligram, 1 Every 1 Week(S)		Not Reported
	Methotrexate			S	Unknown	12 Milligram, 1 Every 1 Week(S)		Not Reported
	Orencia			S	Unknown	78 Milligram, 1 Every 1 Week(S)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	1000 Milligram, 2 Every 1day(S)		Not Reported

Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Actemra	S	Unknown	680 Milligram, 1 Every 1month(S)	Not Reported
Actemra	S	Unknown	360 Milligram, 1 Every 1month(S)	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, 1 Every Week (S)	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, 1 Every Week (S)	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, 1 Every Week (S)	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram	Not Reported
Methotrexate	S	Subcutaneous	50 Milligram, Once A Day	Not Reported
Methotrexate	S	Subcutaneous	780 Milligram, Once A Day	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	10 Milligram, 1 Every Week (S)	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Ciclosporin	C	Unknown	150 Milligram, 1 Every 1 Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16080822	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-012964			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; C-Reactive Protein Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Hepatic	Celecoxib Capsules			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, 2 Everey 1 Week	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	2 Milligram, Once A Day	Not Reported
	Hydromorphone	C	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16081413	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-013665		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Contraindicated Product Administered; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug	Gabapentin			S	Oral	100 Milligram, Two Times A Day		Aurobindo
	Celecoxib Capsules			S	Oral	Unk		Aurobindo
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, Every 1 Month		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Celebrex			S	Unknown	Occlusive Dressing Technique		Not Reported

Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Incorrect Route Of Product Administration; Infection; Nausea; Off Label Use; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Milligram, Once A Day	Not Reported
	Enbrel	S	Unknown	50 Milligram, Every Week	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	1 Dosage Form, Every Week	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Every 3 Weeks	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Every 3 Weeks	Not Reported
	Nortriptyline Hydrochloride	S	Oral	10 Milligram	Not Reported
	Apo-Gabapentin	S	Oral	100 Milligram, Two Times A Day	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, 1 Every One Month	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Every 3 Weeks	Not Reported
	Orencia	S	Vaginal	750 Milligram, Every 1 Month	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Every 4 Weeks	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
	Sulfasalazine	S	Oral	2.5 Milligram, Once A Day	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Once A Day	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Two Times A Day	Not Reported
	Vitamin B1	S	Unknown	Unk	Not Reported

Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Once A Day	Not Reported
Omega-3	S	Unknown	Unk	Not Reported
Omega-3	S	Unknown	1200 Milligram, Two Times A Day	Not Reported
Fentanyl Matrix	S	Unknown	Unk	Not Reported
Acetaminophen;Oxycodone Hydrochloride	C	Unknown	1 Dosage Form	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	70 Milligram, Every 1 Month	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Every 1 Month	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750.0 Milligram, 1 Every 4 Weeks	Not Reported
Actonel	C	Unknown	36 Milligram, Every Week	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	1 Dosage Form, Once A Day	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram, Once A Day	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	Unk Unk, Once A Day	Not Reported
Ergocalciferol	C	Unknown	400 International Unit, Once A Day	Not Reported
Ergocalciferol	C	Unknown	Unk Unk, Once A Day	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Milligram, Two Times A Day	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	400 International Unit, Once A Day	Not Reported
Ferrous Gluconate	C	Unknown	300 Milligram, Once A Day	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Milligram	Not Reported
Nasonex	C	Nasal	2 Dosage Form, Two Times A Day	Not Reported
Omega-3 Fatty Acids	C	Unknown	1200 Milligram, Two Times A Day	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Milligram, Once A Day	Not Reported

Perphenazine	C	Oral	10 Milligram	Not Reported
Prednisone	C	Unknown	5 Milligram, Once A Day	Not Reported
Prednisone	C	Unknown	5 Gigabecquerel, Once A Day	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Once A Day	Not Reported
Tylenol	C	Oral	1000 Milligram, Once A Day	Not Reported
Vitamin B12	C	Unknown	Unk	Not Reported
Vitamin A	C	Unknown	Unk	Not Reported
Percocet	C	Unknown	Unk	Not Reported
Vitamin D 3	C	Unknown	Unk	Not Reported
Lomotil	C	Unknown	Unk	Not Reported
Oxycocet	C	Unknown	Unk	Not Reported
Vitamin C	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
Ferrous Fumarate	C	Unknown	Unk	Not Reported
Ferrous Fumarate	C	Unknown	300 Milligram	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Vitamin B3	C	Unknown	Unk	Not Reported
Vitamin B6	C	Unknown	Unk	Not Reported
Vitamin E	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Calcium	C	Unknown	Unk	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Milligram, Two Times A Day	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported

	Sodium	C	Unknown	Unk	Not Reported
	Ascorbic Acid	C	Unknown	Unk	Not Reported
	Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown	1200.0 Milligram, Two Times A Day	Not Reported
	Thiamine Mononitrate	C	Unknown	Unk	Not Reported
	Nortriptyline Hydrochloride	C	Oral	40 Milligram, Once A Day	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Milligram	Not Reported
	Risedronate Sodium	C	Unknown	36 Milligram, Every Week	Not Reported
	Xeljanz	C	Oral	5 Milligram, Two Times A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16205757	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-020198		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Amlodipine Tablets			S	Oral	Unk, 1 Every 1 Day		Aurobindo
	Amlodipine Tablets			S	Oral	5 Milligram, Once A Day		Aurobindo
	Asacol			S	Unknown	800 Milligram, 3 Every 1 Day		Not Reported
	Asacol			S	Unknown	800 Milligram, 3 Every 2 Day		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Diamicron			S	Unknown	Unk		Not Reported
	Gliclazide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Every Week		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not	1000 Milligram		Not Reported

			otherwise specified)		
	Ferrous Gluconate	C	Unknown	Unk	Not Reported
	Ebastine	C	Unknown	Unk	Not Reported
	Depo-Medrol	C	Intra-articular	Unk	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Diphenhydramine	C	Oral	50 Milligram	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Oral	650 Milligram	Not Reported
	Bisoprolol Fumarate	C	Unknown	Unk	Not Reported
	Atacand Plus	C	Unknown	Unk	Not Reported
	Crestor	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Amlodipine Besilate	C	Unknown	Unk, 1 Every 1 Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16206143	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-019772			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Celecoxib Capsules			S	Oral	200 Milligram, Two Times A Day		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16347402	EXPEDITED (15-DAY)		OT	CA-SA-2019SA139156		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Condition Aggravated; Drug Intolerance; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Sarilumab			S		20 Mg, Qow		Sanofi
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Leflunomide			S	Oral			Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Sulfasalazine			S				Not Reported
	Esomeprazole Magnesium Trihydrate			S				Not Reported
	Nicotinamide			S				Not Reported
	Thiamine Hydrochloride			S				Not Reported
	Esomeprazole Sodium			S				Not Reported
	Folic Acid			S				Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Qw		Not Reported
	Azathioprine			S				Not Reported
	Ciclosporin			S				Not Reported
	Enbrel			S				Not Reported
	Adalimumab			C				Not Reported
	Ergocalciferol			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Metformin			C				Not Reported
	Nexium [Esomeprazole Sodium]			C				Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Magnesium			C		Unk		Not Reported
	Gold			C				Not Reported
	Vitamin A [Retinol]			C				Not Reported
	Vitamin C [Ascorbic Acid]			C				Not Reported
	Dexpanthenol			C				Not Reported
	Esomeprazole Magnesium Trihydrate			C				Not Reported
	Nexium [Esomeprazole Magnesium]			C				Not Reported

	Riboflavin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16387694	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-029951		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Alendronic Acid			S	Unknown	70 Milligram, Every Week		Aurobindo
	Actemra			S	Unknown	360 Milligram, 1 Every 1 Month(S)		Not Reported
	Actemra			S	Unknown	680 Milligram, Once A Day, 1 Every 1 Month(S)		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Every Week		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every 1 Week(S)		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 1 Every 2 Week(S)		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	10.0 Milligram, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	10.0 Milligram, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	15.0 Milligram, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	12.0 Milligram, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	10.0 Milligram, Every Week		Not Reported

	Myochrysine	S	Intramuscular	50.0 Milligram, 1 Every 1 Month(S)	Not Reported
	Myochrysine	S			Not Reported
	Orencia	S	Unknown	780.0 Milligram, Every Week	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000.0 Milligram, Two Times A Day	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	10.0 Milligram, Daily	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Ciclosporin	C	Unknown	150 Milligram, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16388032	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-030631		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion	Alendronic Acid Tablets			S	Oral	Unk		Aurobindo
	Alendronic Acid Tablets			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown	25 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone			S	Oral	Unk		Not Reported
	Cortisone Acetate			S	Topical	25 Milligram		Not Reported

Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Desoximetasone	S	Oral	Unk	Not Reported
	Diclofenac Sodium	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram Once In A Week	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Golimumab	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
	Hydrocortisone Acetate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram, Once A Day	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Once A Day	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Paracetamol	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
	Prednisone	S	Oral	25 Milligram	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	10 Milligram, Once A Day	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not	Unk	Not Reported

			otherwise specified)		
	Rituxan	S	Unknown	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Sulfathalidine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Two Times A Day	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Topicort	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Two Times A Day	Not Reported
	Atasol [Paracetamol]	C	Unknown	Unk	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Salazopyrin	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16440716	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2822523-00		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16729866	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2896155-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16758967	EXPEDITED (15-DAY)		OT	PHHY2019CA200445			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gastric Disorder; Hepatic	Lopresor			S	Unknown	Unk		Novartis
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Clindamycin			S	Unknown	Unk		Not Reported
	Codeine Phosphate			S	Unknown	Unk		Not Reported
	Enalapril Maleate			S	Unknown	Unk		Not Reported

Steatosis; Hypertension; Malaise; Nausea; Rash	Losartan Potassium	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Qd	Not Reported
	Moxifloxacin Hydrochloride	S	Unknown	Unk	Not Reported
	Isoniazid	S	Unknown	Unk	Not Reported
	Keflex	S	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	S	Unknown	Unk	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Penicillin	S	Unknown	Unk	Not Reported
	Pariet	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Hydrochlorothiazide	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Biaxin	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Cipro	C	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Hydroxyquinoline Sulfate	C	Unknown	Unk	Not Reported
	Iron Sucrose	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16820448	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3439		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Cimzia	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Dorzolamide Hydrochloride And Timolol Maleate	C	Unknown	Not Reported
	Estrogel	C	Unknown	Not Reported
	Furosemide	C	Unknown	Not Reported
	Morphine	C	Unknown	Not Reported
	Potassium Chloride	C	Unknown	Not Reported
	Valsartan	C	Unknown	Not Reported
	Xalatan	C	Unknown	Not Reported
	Zingiber Officinale	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16866723	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3761			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Arthritis	Actemra	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17001941	EXPEDITED (15-DAY)		OT	US-ABBVIE-19K-163-2989075-00		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Dry Eye; Dry Mouth; Fatigue; Finger Deformity; Impaired Driving Ability; Macular Degeneration; Pain In Extremity; Rheumatoid Arthritis; Rheumatoid Nodule; Somnolence	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Levothyroxin			C				Not Reported
	Raloxifene			C				Not Reported
	Lidoderm			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17099946	EXPEDITED (15-DAY)		HO, OT	CA-COVIS PHARMA B.V.-2019COV00285		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Asthma; Atelectasis; Blood Disorder; Blood Immunoglobulin E Increased; Bronchial Wall	Alvesco			S	Respiratory (inhalation)	200 Mg, 1x/Day		Covis
	Omnaris			S	Nasal	50 Mg, Unk		Covis
	Pantoloc			S		40 Mg, Unk		Not Reported

Thickening; Bronchiolitis; Condition Aggravated; Cough; Dysphonia; Dyspnoea; Eosinophil Count Increased; Eosinophilic Granulomatosis With Polyangiitis; Fungal Infection; Infection Parasitic; Inflammation; Malaise; Oropharyngeal Pain; Pneumonia; Pneumonitis; Productive Cough; Secretion Discharge; Sinusitis; Skin Disorder; Sleep Disorder Due To A General Medical Condition; Spirometry Abnormal; Suprapubic Pain; Systemic Inflammatory Response Syndrome; Therapeutic Product Effect Incomplete; Underweight; Vasculitis; Weight Decreased; Wheezing	Ivermectin	S		Unk	Not Reported
	Plaquenil	S		Unk	Not Reported
	Prednisone	S	Oral	5 Mg, Unk	Not Reported
	Prednisone	S		50 Mg, Unk	Not Reported
	Salbutamol Sulfate	S		100 Mg, Unk	Not Reported
	Umeclidinium Bromide	S		62.5 Mg, Unk	Not Reported
	Zenhale	S		Unk, 2x/Day	Not Reported
	Sulfasalazine	C			Not Reported
	Arava	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17440774	EXPEDITED (15-DAY)		HO, LT, OT	CA-APOTEX-2018AP013701		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity;	Minocycline			S	Unknown	Unk		Not Reported
	Oxycodone			S	Unknown	10 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Leflunomide			S				Apotex
	Leflunomide			S	Unknown	Unk		Not Reported

Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Leflunomide	S			Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Actemra	S			Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Marijuana	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S			Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Unk	Not Reported
	Plaquenil /00072602/	S			Not Reported
	Plaquenil /00072602/	S			Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S			Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S			Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S			Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S			Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported

Sodium Aurothiomalate	S				Not Reported
Arava	S	Unknown	Unk		Not Reported
Arava	S				Not Reported
Rituximab	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	Unk, Bid		Not Reported
Lyrica	C	Oral	Unk		Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17523584	EXPEDITED (15-DAY)		OT	CA-ROCHE-2564553			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17526969	EXPEDITED (15-DAY)		HO	DE-CELLTRION INC.-2020DE020115			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Anaemia; Arthralgia; Fall; Lower Limb Fracture; Occult Blood Positive; Osteoarthritis; Pruritus; Urinary Tract Infection	Rituximab (Unknown)		S	Unknown	500 Mg, Unk	Not Reported
	Methotrexate		S	Unknown	7.5 Mg, Unk	Not Reported
	Methotrexate		S	Unknown	5 Mg, Unk	Not Reported
	Methotrexate		S	Unknown	7.5 Mg, Unk	Not Reported
	Methotrexate		S	Unknown	5 Mg, Unk	Not Reported
	Methotrexate		S	Unknown	2.5 Mg, Unk	Not Reported
	Methotrexate		S	Unknown	2.5 Mg, Unk	Not Reported
	Mabthera		S	Unknown	500 Mg, Unk	Not Reported
	Mabthera		S	Unknown	500 Mg, Unk	Not Reported
	Mabthera		S	Unknown	500 Mg, Unk	Not Reported
	Hydroxychloroquine		S	Unknown	400 Mg, Unk	Not Reported
	Hydroxychloroquine		S	Unknown	400 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17543429	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2497274-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fall; Fear Of Injection; Joint Swelling; Lower Limb Fracture; Malaise; Mammoplasty; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Urticaria	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17553452	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201805-001630			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia;	Hydroxychloroquine Sulfate			S	Oral	Unk		Concordia

Dizziness; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fear Of Injection; Joint Swelling; Loss Of Personal Independence In Daily Activities; Oedema Peripheral; Pain In Extremity; Rheumatoid Arthritis; Stress; Vomiting	(Authorized Generic),Plaquenil					
	Arava	S	Oral	Unk		Not Reported
	Celecoxib	S	Unknown	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Methotrexate	S	Oral	25 Mg, Weekly		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Prednisone	S	Oral	5 Mg, Qd		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Domperidone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17553454	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201805-001673			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	25 Mg, Weekly		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Tofacitinib			S	Unknown	Unk		Not Reported
	Leflunomide			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17553635	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567770			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Ill-Defined Disorder; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554154	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205022		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	7.1429 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554157	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1205088			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Drug Ineffective; Impaired Work Ability; Pyoderma Gangrenosum; Rheumatoid Arthritis	Methotrexate		S	Unknown	Barr
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Prednisone		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554179	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205203			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Moxifloxacin Hydrochloride			S	Oral			Teva
	Amoxicillin Trihydrate/Clavulanate Potassium			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554197	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204339			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

Orencia	S	Unknown			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Tocilizumab	S	Unknown			Not Reported
Tofacitinib	S	Unknown			Not Reported
Xeljanz	S	Unknown			Not Reported
Rabeprazole Sodium	C	Oral	20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554199	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204340			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Bifidobacterium Bifidum			C				Not Reported
	Loperamide			C	Oral			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554209	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020112925		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Drug Hypersensitivity; Drug Ineffective; Dysbiosis; Fatigue; Infection; Inflammation; Insomnia; Maternal Exposure During Pregnancy; Nausea; Pain; Psoriasis; Rheumatoid Factor Positive; Synovitis; Thyroid Disorder	Enbrel			S	Unknown	50 Milligram		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram		Pfizer
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Naproxen			S	Unknown	500 Milligram, Tid		Not Reported
	Naproxen			S	Unknown	500 Milligram, Tid		Not Reported
	Penicillin G [Benzylpenicillin]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported
	Synthroid			C		Unk		Not Reported
	Tramadol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554234	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205191		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554424	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1205198		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ilaris Single-Use Vial			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554449	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021302			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Naproxen Sodium			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral	5.0 Milligram 2 Every 1 Days		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554632	EXPEDITED (15-DAY)		OT	NVSC2020CA072976		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Cyclosporine			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported

Plaquenil	S	Oral	20 Mg		Not Reported
Remicade	S	Intravenous (not otherwise specified)	3.0 Mg/Kg		Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
Enbrel	S	Subcutaneous	50 Mg 1 Every 1 Weeks		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554671	EXPEDITED (15-DAY)		OT	CA-ROCHE-2565792		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Skin Reaction; Skin Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554843	EXPEDITED (15-DAY)		OT	CA-ROCHE-2565710			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Limb Deformity; Musculoskeletal Pain;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

Pain; Pain In Extremity; Pruritus; Rash; Squamous Cell Carcinoma; Treatment Failure	Methotrexate	S	Oral	Not Reported
	Neoral	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Citalopram Hydrobromide	C	Unknown	Not Reported
	Citalopram Hydrobromide	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17555043	EXPEDITED (15-DAY)		HO	CA-ROCHE-2565721		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naprosyn [Naproxen]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17555247	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567695		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Intolerance; Herpes Zoster; Therapeutic Product Effect Decreased	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Lyrica	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17555303	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568898		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alopecia; Anxiety; Asthenia; Depression; Drug Ineffective; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17555514	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1412		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Pain; Rash; Rheumatoid Arthritis; Sleep Disorder	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Oral			Not Reported
	Minocin			S	Unknown			Not Reported
	Minocycline Hcl			S	Unknown			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ustekinumab			S	Unknown			Not Reported
	Ustekinumab			S	Subcutaneous			Not Reported
	Tocilizumab			S	Unknown			Not Reported

Certolizumab Pegol	S	Subcutaneous	Not Reported
Myochrysine	S	Parenteral	Not Reported
Myochrysine	S	Subcutaneous	Not Reported
Myochrysine	S	Unknown	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Stelara	S	Unknown	Not Reported
Stelara	S	Subcutaneous	Not Reported
Rituximab	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Apremilast	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	C	Unknown	Not Reported
Abatacept	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17555803	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1027221		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Pyrexia;	Prednisone			S		25 Mg, Qd		Not Reported
	Prednisone			S		(7.5 Mg Qd, Dose		Not Reported

Systemic Lupus Erythematosus				Tapering)	
	Prednisone		S	Unk (50 Mg Qd, Tapering Dose)	Not Reported
	Prednisone		S	15 Mg, Qd	Not Reported
	Prednisone		S	Unk (25 Mg Qd, Dose Tapering)	Not Reported
	Prednisone		S	(15 Mg Qd, Dose Tapering)	Not Reported
	Prednisone		S	Unk Unk (12.5 Mg Qd, Dose Tapering)	Not Reported
	Prednisone		S	Unk Unk (10 Mg Qd, Dose Tapering)	Not Reported
	Tacrolimus		S	Unk Unk, Qd	Not Reported
	Mycophenolate Mofetil		S	Unk Unk, Qd	Not Reported
	Hydroxychloroquine Sulfate		S	400 Mg, Qd	Mylan
	Methylprednisolone		C	Unk (Pulses)	Mylan
	Rituximab		C	Unk	Mylan
	Immunoglobulin I.V		C	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17555876	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020114584			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Hepatitis B Reactivation; Inflammation; Malaise; Stomatitis; Weight Decreased	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17556462	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2020M1027359			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Off Label Use; Respiratory Tract Infection; Vomiting	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Abatacept			S	Unknown	Unk		Mylan
	Roactemra			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17557419	NON-EXPEDITED			NVSC2020US076875		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Tacrolimus			S	Topical	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17557715	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205280			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Mobility Decreased; Osteomyelitis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Naproxen			C	Unknown			Not Reported
	Naproxen			C	Unknown	250 Milligram Daily;		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Hydrocortisone Valerate			C	Unknown			Not Reported
	Hydromorphone			C				Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Lyderm			C	Unknown			Not Reported

	Prednisone	C	Unknown	Not Reported
	Sodium Aurothiomalate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17557720	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205274		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Leucovorin [Folinic Acid]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17557725	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205434			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain In Extremity; Peripheral Swelling	Methotrexate			S	Unknown			Barr
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17557745	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205311		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Infection; Pharyngeal Oedema; Rheumatoid Arthritis	Methotrexate	S	Unknown		Barr
	Arava	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17557806	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205513			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Gait Disturbance; Headache; Influenza Like Illness; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Osteoarthritis; Rheumatoid Arthritis; Weight Fluctuation	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actemra			C				Not Reported
	Actemra			C				Not Reported
	Enbrel			C	Subcutaneous	50 Milligram Daily;		Not Reported
	Humira			C	Subcutaneous			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17558048	NON-EXPEDITED		OT	NVSC2020US076308		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Diarrhoea; Gait Inability; Herpes Zoster; Rash; Skin Necrosis	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Novartis
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

Prednisone	S	Unknown	Unk		Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	Unk		Not Reported
Prednisolone	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17558470	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020114627		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation; Choking; Cough; Drug Ineffective; Drug Intolerance; Facial Pain; Fatigue; Fibromyalgia; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Insomnia; Joint Range Of Motion Decreased; Melanocytic Naevus; Nasal Discomfort; Nausea; Night Sweats; Oropharyngeal Discomfort; Pain; Pain In Extremity; Pain In Jaw; Peripheral Coldness; Rhinorrhoea; Skin Mass	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2 Every 1 Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 1 Every 1 Day		Pfizer
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Morphine			C	Unknown	Unk		Not Reported
	Tylenol [Paracetamol]			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	12956625	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2016AP014656		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug	Bisoprolol			S	Unknown	Unk		Not Reported

Hypersensitivity; Drug Intolerance; Fatigue; Hypersensitivity; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Vomiting	Leflunomide	S	Unknown	Unk	Apotex
	Norfloxacin	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Apo-Norflox	S	Unknown	400 Mg, Unk	Apotex
	Apo-Bisoprolol	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Apotex
	Levofloxacin	S	Unknown	Unk	Apotex
	Apo-Prednisone	S	Unknown	Unk	Apotex
	Erythromycin	S	Unknown	Unk	Not Reported
	Metronidazole	S	Unknown	Unk	Not Reported
	Pregabalin	S	Unknown	Unk	Not Reported
	Cefaclor	S	Unknown	Unk	Not Reported
	Celecoxib	S	Oral	200 Mg, Qd	Apotex
	Arthrotec	S	Unknown	Unk	Not Reported
	Ceclor	S	Unknown	Unk	Not Reported
	Celebrex	S	Oral	200 Mg, Qd	Not Reported
	Demerol	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	400 Mg, Every Two Months	Not Reported
	Humira	S	Subcutaneous	400 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unknown	Not Reported
	Meperidine Hcl	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	20 Mg, Q.Wk	Not Reported
	Metronidazole	S	Unknown	5 Mg/Ml, Unk	Not Reported
	Plaquenil /00072602/	S	Oral	400 Mg, Qd	Not Reported
	Lyrica	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Flagyl /00012501/	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported

	Erythromycin Estolate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	13516429	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-037987			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased; Off Label Use	Abatacept			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	13823542	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2252		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Codeine	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Lyrica	C	Oral	Not Reported
	Lyrica	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	13929206	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Rituximab	S	Intravenous drip		Not Reported
Imuran	C	Unknown		Not Reported
Arthrotec	C	Unknown		Not Reported
Ergocalciferol	C	Unknown		Not Reported
Azathioprine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	14223269	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021499			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	640 Mg, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	14236211	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3856			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug	Methotrexate (Trade Name			S	Oral			Not Reported

Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Unknown)			
	Enbrel	S	Subcutaneous	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Meloxicam	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Mobicox	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	14545702	EXPEDITED (15-DAY)		OT	CA-ROCHE-1715783		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain Upper; Blood Pressure Diastolic Increased; Blood Pressure Diastolic Increased; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Increased; Blood Pressure Increased; Cough; Decreased Appetite; Epistaxis; Headache; Heart Rate Increased; Influenza Like Illness; Infusion Related Reaction; Infusion Site Pain; Medication Error; Nausea; Pain; Platelet Count Decreased; Pruritus; Pyrexia; Sensation Of Foreign Body; Vomiting; Weight	Rituxan			S	Intravenous (not otherwise specified)	Last Dose: 21/Sep/2015, Most Recent Dose On 06/Jun/2017 (683 Mg)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Last Dose: 21/Sep/2015		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

Increased; Weight Increased	Acetaminophen	C	Oral	Not Reported
	Acetaminophen	C	Oral	Not Reported
	Methotrexate	C		Not Reported
	Folic Acid	C		Not Reported
	Atovaquone	C		Not Reported
	Alendronate	C		Not Reported
	Vit D3	C		Not Reported
	Diphenhydramine Hcl	C	Oral	Not Reported
	Diphenhydramine Hcl	C	Oral	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	14727278	EXPEDITED (15-DAY)		HO, OT	JP-GLAXOSMITHKLINE-JP2018JPN056741		45 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis; Cytomegalovirus Infection; Neutrophil Count Decreased; Pancreatitis Acute; Pneumocystis Jirovecii Pneumonia; White Blood Cell Count Decreased; White Blood Cell Count Decreased	Belimumab			S	Intravenous drip	10 Mg/Kg, Every Two Weeks		Glaxosmithkline
	Belimumab			S	Intravenous drip	10 Mg/Kg, Every Four Weeks		Glaxosmithkline
	Belimumab			S	Intravenous drip	10 Mg/Kg, Every Four Weeks		Glaxosmithkline
	Belimumab			S	Intravenous drip	10 Mg/Kg		Glaxosmithkline
	Belimumab			S	Intravenous drip	10 Mg/Kg, 1d		Glaxosmithkline
	Belimumab			S	Intravenous drip	10 Mg/Kg		Glaxosmithkline
	Furosemide			S	Oral	Unk		Glaxosmithkline
	Prednisolone			S	Oral	Unk		Glaxosmithkline
	Prednisolone			S	Oral	70 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Oral	60 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Oral	50 Mg, 1d		Glaxosmithkline

Prednisolone	S	Oral	40 Mg, 1d	Glaxosmithkline
Prednisolone	S	Intravenous drip	40 Mg, 1d	Glaxosmithkline
Prednisolone	S	Intravenous drip	60 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	40 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	30 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	25 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	22.5 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	20 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	25 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	40 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	60 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	40 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	35 Mg, 1d	Glaxosmithkline
Prograf	S	Oral	Unk	Not Reported
Cellcept	S	Oral	Unk	Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Meropenem	S	Intravenous drip	1 G, Tid	Not Reported
Meropenem	S	Intravenous drip	Unk	Not Reported
Miraclid	S	Intravenous drip	300000 Iu, 1d	Not Reported
Omeprazole	S	Intravenous drip	40 Mg, 1d	Glaxosmithkline
Solu Medrol	C	Intravenous (not otherwise specified)	1000 Mg, 1d	Not Reported
Solu Medrol	C	Intravenous (not otherwise specified)	125 Mg, 1d	Not Reported
Valixa	C		Unk	Not Reported
Bonalon	C		Unk	Not Reported
Novorapid	C		Unk	Not Reported
Baktar	C		1 Df, We	Not Reported
Baktar	C			Not Reported
Daikenchuto	C		Unk	Not Reported

Sodium Picosulfate Hydrate	C	Unk	Not Reported
Tenelia	C	Unk	Not Reported
Pitavastatin Calcium	C	Unk	Not Reported
Cardenalin	C	Unk	Not Reported
Rabeprazole Sodium	C	Unk	Not Reported
Azilva	C	Unk	Not Reported
Amlodipine Besilate	C	Unk	Not Reported
Azelnidipine	C	Unk	Not Reported
Carvedilol	C	Unk	Not Reported
Bayaspirin	C	Unk	Not Reported
Sennoside	C	Unk	Not Reported
Insulin Glargine (Genetical Recombination)	C	Unk	Not Reported
Spironolactone	C	Unk	Not Reported
Humalog	C	Unk	Not Reported
Persantin-L	C	Unk	Not Reported
Feburic	C	Unk	Not Reported
Bonviva	C	Unk	Not Reported
Novolin R	C	Unk	Not Reported
Trazenta	C	Unk	Not Reported
Polaprezinc	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	15207582	NON-EXPEDITED			US-PFIZER INC-2018300600		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Cimzia			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Imuran			S		Unk		Not Reported

Plaquenil	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	15605753	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3227		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Treatment Failure; Uveitis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Prednisone	C	Unknown	Not Reported
	Rabeprazole Sodium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	15675159	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2495		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Tolerance Decreased; Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

	Coversyl	C	Unknown		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported
	Cephalexine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	15962909	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013651		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Osteoarthritis; Synovitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200.0 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	10 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Simponi			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, 2 Every 1 Day		Not Reported
	Hydroxychloroquine Sulfate			C	Oral	200 Milligram, 2 Every 1 Day		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	16082171	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-06027		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchiectasis; Bursitis Infective; Crying; Infection;	Infliximab			S	Unknown	Unknown		Not Reported

Inflammation; Leg Amputation; Localised Infection; Osteoporosis; Peripheral Vascular Disorder; Pneumonia; Respiratory Tract Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Therapeutic Product Effect Incomplete	Arava	S	Unknown		Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Prednisone	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Remicade	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Acidophilus	C	Unknown	Unknown	Not Reported
	Aspirin	C	Unknown	Unknown	Not Reported
	Calcium	C	Unknown	Unknown	Not Reported
	Deflazacort	C	Unknown		Not Reported
	Dilaudid	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown	Unknown	Not Reported
	Hydromorphone Hydrochloride	C	Unknown		Not Reported
	Hydromorphone Hydrochloride	C	Unknown		Not Reported
	Januvia	C	Unknown	Unknown	Not Reported
	Lidocaine	C	Topical		Not Reported
	Metronidazole	C	Unknown	Unknown	Not Reported
	Nitroglycerin	C	Unknown	Unknkown	Not Reported
	Pantoloc	C	Unknown	Unknown	Not Reported
	Pregabalin	C	Unknown		Not Reported
	Pregabalin	C			Not Reported
	Pregabalin	C			Not Reported
	Risedronate	C	Unknown		Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported
	Rosuvastatin Calcium	C	Unknown	Unknown	Not Reported

Salbutamol	C	Unknown	Unknown		Not Reported
Salicylic Acid/Triamcinolone Acetonide	C	Intra-articular			Not Reported
Triamcinolone	C	Unknown			Not Reported
Tylenol	C	Unknown	Unknown		Not Reported
Xeljanz	C	Oral			Not Reported
Calcium Gluconate	C	Unknown	Unknown		Not Reported
Lactobacillus Acidophilus	C	Unknown	Unknown		Not Reported
Risedronate Sodium	C	Unknown	Unknown		Not Reported
Salicylic Acid	C	Unknown	Unknown		Not Reported
Triamcinolone Acetonide	C	Intra-articular	Suspension, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	16444894	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033815		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Dermatomyositis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Intentional Product Use Issue; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Thrombosis; Uterine Disorder; Weight Increased	Metformin			S	Unknown	Unk		Aurobindo
	Metformin			S				Aurobindo
	Cymbalta			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Coumadin			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Xarelto			C	Unknown	Unk		Not Reported
	Imuran			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	16866958	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-092201		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Abatacept			S	Unknown			Bristol Myers Squibb
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Kevzara			S	Unknown	Unk		Not Reported
	Mefenamic Acid			S	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Rabeprazole Sodium			C	Oral	20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17124253	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-113880			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Qwk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Q2wk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram		Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk (12.5 Milligram, 4 Every 1 Week)		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5 Milligram/Kilogram, Qd		Not Reported
	Human Immunoglobulin (Immunoglobulin Human Normal)			S	Unknown	Unk		Not Reported
	Human Immunoglobulin (Immunoglobulin Human Normal)			S	Intravenous (not otherwise specified)	70 Gram		Not Reported
	Infliximab			S	Unknown	5 Milligram		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram/Sq. Meter, Qwk		Not Reported
	Naproxen			S	Unknown			Not Reported
	Prednisone			S	Oral	10 Milligram, Qd (5		Not Reported

				Milligram, 2 Every 1 Day)	
	Prednisone	S	Oral	3 Milligram, Bid	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Triamcinolone Hexacetonide	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17390832	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0682		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tylenol			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17397400	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA032774			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug	Cosentyx			S	Unknown	Unk		Novartis

Ineffective; Drug-Induced Liver Injury	Leflunomide		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Otezla		S	Oral	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Stelara		S	Subcutaneous	Unk	Not Reported
	Xeljanz		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17450142	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1058		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Hypersensitivity; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapy Non-Responder; Treatment Failure; Wound	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

		otherwise specified)	
Actemra	S	Unknown	Not Reported
Alendronate Sodium	S	Oral	Not Reported
Atasol [Paracetamol]	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cetirizine;Hydrochloride;Pseudo ephedrine	S	Unknown	Not Reported
Cortisone Acetate	S	Topical	Not Reported
Desoximetasone	S	Oral	Not Reported
Diclofenac	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfathalidine	S	Oral	Not Reported
Sulfathalidine	S	Oral	Not Reported
Topicort	S	Subcutaneous	Not Reported

Fosamax	S	Oral			Not Reported
Fosamax	S	Oral			Not Reported
Apo-Prednisone	S	Unknown			Not Reported
Vitamin C	C	Unknown			Not Reported
Vitamin D	C	Unknown			Not Reported
Alaskan Salmon Oil	C	Unknown			Not Reported
Glucosamine	C	Unknown			Not Reported
Lansoprazole	C	Unknown			Not Reported
Ativan	C	Unknown	As Needed		Not Reported
Salazopyrin	C	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17557868	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-013437		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Prescribed Underdose; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Celecoxib Capsules			S	Unknown	Unk		Aurobindo
	Celecoxib Capsules			S				Aurobindo
	Anakinra			S	Unknown	100 Milligram		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	10 Milligram, Once A Day		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Once A Day		Not Reported
	Apo-Prednisone			S	Unknown	7 Milligram, Once A Day		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S				Not Reported
	Celebrex			S	Unknown	200 Milligram		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Etanercept			S	Subcutaneous	25 Milligram		Not Reported

Hydroxychloroquine	S	Unknown	300 Milligram, Once A Day	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Every Week	Not Reported
Methotrexate	S	Subcutaneous	1 Milliliter, Every Week	Not Reported
Orencia	S	Intravenous (not otherwise specified)	0.75 Milligram, 1 Every 1 Month	Not Reported
Prednisone	S	Unknown	7 Milligram, Once A Day	Not Reported
Remicade	S	Intravenous (not otherwise specified)	7 Milligram, Once A Day	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, 1 Every 1 Month	Not Reported
Xeljanz	S	Oral	5 Milligram, Two Times A Day	Not Reported
Altace	C	Unknown	5 Milligram	Not Reported
Altace	C	Unknown	10 Milligram	Not Reported
Apo-Gabapentin	C	Oral	100 Milligram	Not Reported
Apo-Gabapentin	C	Unknown	300 Milligram	Not Reported
Acetaminophen;Codeine Phosphate	C	Unknown	Unk	Not Reported
Atorvastatin Calcium	C	Oral	40 Milligram, Once A Day	Not Reported
Atorvastatin Calcium	C	Unknown	40 Milligram, Once A Day	Not Reported
Citalopram Hydrobromide	C	Unknown	20 Milligram	Not Reported
Conjugated Estrogens	C	Unknown	0.625 Milligram	Not Reported
Conjugated Estrogens	C	Unknown	20 Milligram	Not Reported
Cymbalta	C	Unknown	30 Milligram, Four Times/Day	Not Reported
Cymbalta	C	Unknown	60 Milligram	Not Reported
Cymbalta	C	Unknown	120 Milligram, Once A Day	Not Reported
Cipralex	C	Unknown	20 Milligram	Not Reported

Escitalopram	C	Unknown	10 Milligram		Not Reported
Estrace	C	Unknown	0.5 Milligram		Not Reported
Gabapentin	C	Oral	100 Milligram		Not Reported
Gabapentin	C	Unknown	3000 Milligram		Not Reported
Hydrochlorothiazide	C	Unknown	12.5 Milligram		Not Reported
Hydromorphone Hydrochloride	C	Oral	3 Milligram, Two Times A Day		Not Reported
Hydromorphone Hydrochloride	C	Oral	30 Milligram, Two Times A Day		Not Reported
Mupirocin	C	Topical	Unk		Not Reported
Pantoloc	C	Intravenous (not otherwise specified)	20 Milligram, Once A Day		Not Reported
Shark Liver Oil	C	Unknown	Unk		Not Reported
Tapentadol Hydrochloride	C	Unknown	50 Milligram		Not Reported
Taro-Mupirocin	C	Topical	Unk		Not Reported
Tramacet	C	Oral	Unk		Not Reported
Tramadol Hydrochloride	C	Oral	50 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17557974	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201805-001639			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Therapeutic Response Decreased; Therapy Non-Responder	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Concordia
	Hydroxychloroquine			S	Unknown	400 Mg		Concordia
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17558021	EXPEDITED (15-DAY)		HO, OT	CA-ADVANZ PHARMA-GSH201711-006521			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Asthenia; Condition Aggravated; Diarrhoea; Dizziness; Fatigue; Hernia; Pneumonia; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	200 Mg, Bid, Tablet		Concordia
	Apo-Folic			S	Unknown	1 Dosage Form, Biw(Twice A Week)		Not Reported
	Apo-Gabapentin			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Esomeprazole Magnesium Trihydrate			S	Unknown	40 Mg, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, 4 Times In A Week		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Qd		Not Reported
	Xeljanz			S	Oral	5 Mg, Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17558061	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-013432		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid	Alendronic Acid Tablets			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10.0 Milligram		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	400.0 Milligram		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported

Arthritis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	5.0 Milligram	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40.0 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	20.0 Milligram, Once A Day	Not Reported
	Methotrexate	S	Oral	25.0 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Every Week	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400.0 Milligram, Once A Day	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S			Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	1000.0 Milligram, Two Times A Day	Not Reported
	Sulfathalidine	S	Unknown	Unk	Not Reported
	Salazopyrin	C	Unknown	Unk	Not Reported
	Diclofenac	C	Unknown	50.0 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17558697	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021515			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Alendronate Sodium			S	Unknown	Unk		Not Reported
	Cetrizine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17558984	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201806-002196			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia; Rash Maculo-Papular; Toxic Skin Eruption; Vitreous Detachment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd (Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	100 Mg, Qod (Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod (Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd (Film-Coated Tablet)		Concordia

	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Oral	200 Mg, Qod (Film-Coated Tablet)	Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Oral	400 Mg, Qod (Film-Coated Tablet)	Concordia
	Onetram	C		Unk	Not Reported
	Nexium	C		Unk	Not Reported
	Prorenal	C		Unk	Not Reported
	Seroquel	C		Unk	Not Reported
	Magnesium Oxide	C		Unk	Not Reported
	Cefalexin	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559013	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-08978		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rheumatoid Arthritis; Treatment Failure	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous	Unknown		Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Certolizumab Pegol			S	Unknown	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Oral	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported

Hydroxychloroquine Sulfate	S	Oral	Unknown		Not Reported
Imuran	S	Unknown	Unknown		Not Reported
Leflunomide	S	Oral			Not Reported
Methotrexate	S	Unknown	Unknown		Not Reported
Plaquenil	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Sulfasalazine	S	Unknown	Unknown		Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559017	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-08970		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Etanercept			S	Unknown	Unknown		Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Parenteral	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Oral	Unknown		Not Reported

	Methotrexate	S	Parenteral	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Methotrexate	S	Oral	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Arava	C	Unknown	Unknown	Not Reported
	Prednisone	C	Unknown	Unknown	Not Reported
	Tofacitinib	C	Unknown	Unknown	Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559162	EXPEDITED (15-DAY)		OT	CA-ROCHE-2569481		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Simponi	S	Subcutaneous	Not Reported
	Lyrica	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559216	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021540		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559217	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568742			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine Sulfate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559478	EXPEDITED (15-DAY)		OT	CA-ROCHE-2565794		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559517	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568861		89 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Naprosyn [Naproxen]	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Vioxx	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559606	EXPEDITED (15-DAY)		HO, OT	US-APPCO PHARMA LLC-2081773		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559853	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021632		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	20 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Prednisone			S	Oral	5 Milligram, Qd		Not Reported

	Sulfasalazine	S	Unknown	1000 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559938	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2020-1439		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation; Choking; Cough; Drug Ineffective; Drug Intolerance; Facial Pain; Fatigue; Fibromyalgia; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Insomnia; Joint Range Of Motion Decreased; Melanocytic Naevus; Nasal Discomfort; Nausea; Night Sweats; Oropharyngeal Discomfort; Pain; Pain In Extremity; Pain In Jaw; Peripheral Coldness; Rhinorrhoea; Skin Mass	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559980	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021788		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Therapeutic	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Product Effect Incomplete	Apo-Leflunomide		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Naproxen		C	Unknown	500 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559985	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566109			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthma; Drug Ineffective; Encephalitis Viral; Infection; Lung Disorder; Retinal Deposits; Wheezing	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559994	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021821			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560048	EXPEDITED (15-DAY)		OT	GB-ACCORD-176336		29 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Drug Ineffective; Transient Ischaemic Attack; Treatment Failure	Atorvastatin/Atorvastatin Calcium			S	Unknown	Unk		Not Reported
	Clopidogrel			S	Unknown	Unk		Not Reported
	Apixaban			S	Unknown			Not Reported
	Warfarin			S	Unknown	Unk		Not Reported
	Rivaroxaban			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560201	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021912			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Methotrexate	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Remicade	S	Unknown		Not Reported
Rituximab	S	Intravenous drip		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560261	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-202003001629			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glossodynia; Hangnail; Nail Avulsion; Onychoclasis; Sjogren'S Syndrome; Stomatitis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk, Resumption		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560263	EXPEDITED (15-DAY)		HO, OT	FR-ADVANZ PHARMA-202003001668			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Hypersensitivity	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	200 Mg		Concordia
	Nivaquine			C		100 Mg		Not Reported
	Nivaquine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560475	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021879			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulphate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Unknown	5 Milligram, Q12h	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Arava	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560672	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021576		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560673	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021952		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Carotid Arteriosclerosis; Drug Ineffective; Drug Intolerance; Eye Disorder; Herpes Zoster; Joint Swelling; Limb Discomfort; Malaise; Nausea; Nodule; Off Label Use; Osteoarthritis; Rectal Haemorrhage; Rheumatoid Arthritis; Thyroid Cancer	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	2.5 Milligram, Qd		Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561009	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020118255			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Drug Ineffective	Methotrexate Sodium			S	Unknown			Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561066	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020118198			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Atorvastatin Calcium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		200 Mg, 2x/Day		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Monthly		Not Reported
	Alprazolam			C		1 Mg, Unk		Not Reported
	Folic Acid			C		5 Mg, Unk		Not Reported
	Naprosyn [Naproxen]			C		500 Mg, 2x/Day		Not Reported
	Pantoloc [Pantoprazole]			C		Unk		Not Reported
	Prednisone			C		5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561096	EXPEDITED (15-DAY)		OT	CA-SHIRE-CA202009727			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)			Shire
	Azathioprine			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561109	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008889			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Intolerance; Leukopenia	Hydroxychloroquine	S	Oral	Unk		Apotex
	Leflunomide	S	Oral	Unk		Apotex
	Etanercept	C	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported
	Sulfasalazine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561711	EXPEDITED (15-DAY)		HO	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022131			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Intentional Product Use Issue; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	1.5 Gram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561810	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1206362		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Influenza; Injection Site Pain; Pain; Pain In Extremity; Rheumatoid Arthritis; Skin Burning Sensation; Skin Exfoliation	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Hydromorph Contin			C				Not Reported

Prednisone	C		Not Reported
Allopurinol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561811	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1206466			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Alopecia	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			C				Not Reported
	Leflunomide			C				Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561822	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206400		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Sounds Abnormal; Drug Ineffective; Hepatic Enzyme Increased; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)	
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Acetylsalicylic Acid	C	Unknown	Not Reported
	Alprazolam	C	Unknown	Not Reported
	Amlodipine	C	Unknown	5 Milligram Daily; Not Reported
	Asa	C	Unknown	Not Reported
	Bisoprolol Fumarate	C	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Metformin	C	Unknown	Not Reported
	Morphine Sulfate	C	Unknown	Not Reported
	Morphine Sulfate	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Paroxetine	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Risedronate Sodium	C	Unknown	Not Reported
	Simvastatin	C	Unknown	Not Reported
	Telmisartan	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561842	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206475			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lung Disorder; Platelet Count	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported

Decreased; Rheumatoid Arthritis; Septic Shock; Synovitis; White Blood Cell Count Decreased	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown	2 Gram Daily;	Not Reported
	Tofacitinib		S	Unknown	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561854	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206317		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561863	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206324		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthritis; Drug Ineffective; Gait Disturbance; Nerve Compression	Methotrexate	S	Unknown		Barr
	Sulfasalazine	S	Unknown	2 Gram Daily;	Not Reported
	Actemra	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561870	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206272		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Condition Aggravated; Dry Eye; Fatigue; Feeling Abnormal; Gastrointestinal Disorder; Headache; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete; Thirst; Tremor; Upper Respiratory Tract Infection	Methotrexate			S	Unknown			Barr
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Apo-Naproxen			C		1000 Milligram Daily;		Not Reported
	Apo-Prednisone			C				Not Reported
	Desoximetasone			C				Not Reported
	Ergocalciferol			C	Oral			Not Reported
	Folic Acid			C		1 Milligram Daily;		Not Reported
	Leucovorin Calcium			C				Not Reported
	Pantoprazole Magnesium			C		40 Milligram Daily;		Not Reported
	Pantoprazole Magnesium			C		1 Dosage Forms Daily;		Not Reported
	Vitamin C [Ascorbic Acid]			C	Oral			Not Reported
	Wellbutrin			C		300 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561877	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206389			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In	Methotrexate			S	Unknown			Barr

Daily Activities; Treatment Failure	Enbrel		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Tofacitinib		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17562040	NON-EXPEDITED			US-PFIZER INC-2020117515		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Diarrhoea; Drug Hypersensitivity; Nausea; Vomiting	Ciprofloxacin			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17562437	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022525			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Sulfasalazine	S	Unknown			Not Reported
Bifidobacterium Bifidum	C	Unknown			Not Reported
Loperamide	C	Oral			Not Reported
Pantoprazole	C	Unknown	Unk, Tid		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17562446	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020116277		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Acuity Reduced	Dobupal			S		Unk Unk, 1x/Day (1/24)		Pfizer
	Hydrochlorothiazide/Losartan Potassium			S		50 Mg/12.5 Mg		Not Reported
	Eutirox			S		Unk Unk, 1x/Day (1/24)		Not Reported
	Dolquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17562460	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567649			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug-Induced Liver Injury; Dyspepsia	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	300-400 ; Ongoing		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Ongoing		Not Reported
	Simponi			S	Unknown	Ongoing		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17562480	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206591		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Androgenetic Alopecia; Aphthous Ulcer; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Increased; Blood Pressure Systolic Increased; Diffuse Alopecia; Drug Ineffective; Heart Rate Decreased; Infection; Infusion Related Reaction; Nasopharyngitis; Rash; Stomatitis; White Blood Cell Count Decreased	Methotrexate	S	Unknown	Barr
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Asa	C	Unknown	Not Reported
	Bisoprolol	C	Unknown	Not Reported
	Candesartan	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Rosuvastatin Calcium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17562971	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022558		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17563672	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-			Female	CAN

BMS-2020-022540

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17563850	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021523		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation	Orencia			S	Unknown			Bristol Myers Squibb
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported

Rate Increased; Somnolence; Visual Impairment	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Oral	2000 Milligram	Not Reported
	Meloxicam		C	Unknown		Not Reported
	Methotrexate		C	Unknown	25 Milligram, Qwk	Not Reported
	Acetaminophen And Codeine Phosphate		C	Unknown		Not Reported
	Synthyroid		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	13519848	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-000478		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Off Label Use; Photosensitivity Reaction; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Stomatitis; Urticaria	Orencia			S	Unknown			Bristol Myers Squibb
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Oxycodone			S	Unknown	10 Mg, Unk		Not Reported
	Minocycline Hcl			S	Unknown	Unk		Not Reported
	Marijuana			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Cannabis Sativa			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Oxycodone Hydrochloride			S	Unknown	Unk		Not Reported

Hydroxychloroquine Sulphate	S	Unknown	400 Milligram		Not Reported
Hydroxychloroquine Sulphate	S	Unknown	400 Gram		Not Reported
Lyrica	C	Oral	Unk		Not Reported
Prednisone	C	Unknown	Unk, Qd		Not Reported
Xeljanz	C	Oral	5 Mg, Q2wk		Not Reported
Actemra	C	Unknown			Not Reported
Cannabis Sativa	C	Unknown			Not Reported
Enbrel	C	Unknown			Not Reported
Oxycodone	C	Unknown	10 Milligram		Not Reported
Sulfasalazine	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	13594604	EXPEDITED (15-DAY)		OT	CA-ROCHE-1941652		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	13901217	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170125543		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hepatotoxicity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Pain; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Kineret			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Subcutaneous			Not Reported

Apo-Hydroxyquine	S	Subcutaneous	Not Reported
Actonel	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Xeljanz	S	Oral	Not Reported
Risedronate	S	Unknown	Not Reported
Risedronate	S	Unknown	Not Reported
Risedronate Sodium	S	Other	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Adalimumab	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	14326215	NON-EXPEDITED			US-AMGEN-USASP2017190208		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Asa			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Macrobid [Nitrofurantoin]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	15385213	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184735		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	15565611	EXPEDITED (15-DAY)		CA, DS, HO, OT	CA-CELLTRION INC.-2018CA023567			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue;	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
	Xeljanz	S	Unknown	5 Mg, Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Arava	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	15620814	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556952-00		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Actonel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	15625325	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557482-00		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Drug Ineffective; Fatigue; Joint Stiffness; Joint Swelling; Loss Of Personal	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Swelling; Therapeutic Product Effect Incomplete	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Rituxan	C	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	15629661	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557290-00		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

				otherwise specified)	
	Asa		C		Not Reported
	Clonazepam		C	Oral	Not Reported
	Desipramine		C	Unknown	Not Reported
	Nitroglycerin		C		Not Reported
	Rosuvastatin Calcium		C	Oral	Not Reported
	Gabapentin		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	15635193	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105819			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral			Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	25 Mg, Qwk		Not Reported
	Prednisone			C	Unknown	30 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16122724	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Acetaminophen			S	Endocervical			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram, Bid		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Bid		Not Reported
	Sulfasalazine			S	Oral	2000 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Milligram, Bid		Not Reported
	Apo-Prednisone			S	Oral	20 Nanogram		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk, Qwk		Not Reported
	Methotrexate			C	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			C	Unknown	Unk, Q4wk		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported
	Acetaminophen & Cod. Phosp.			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16145460	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2019CA019978			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, Weekly		Not Reported
	Enbrel			S	Unknown	50 Mg, Weekly, Unknown		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Q2wk (End Date: 2011)		Not Reported
	Enbrel			S	Unknown	25 Mg, 2x/Week (End Date: 2011)		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, Unk (1 Every 2 Week)		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Etanercept			S	Unknown	25 Milligram, 2 Times/Wk		Not Reported
	Etanercept			S	Unknown	50 Mg, Weekly		Not Reported
	Celebrex			S		Unk		Not Reported
	Methotrexate Sodium			S	Unknown	12 Mg, Weekly		Not Reported
	Methotrexate Sodium			S	Unknown	12 Mg, Weekly		Not Reported
	Methotrexate Sodium			S	Unknown	12 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	12.5 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	15.5, Weekly		Not Reported
	Methotrexate Sodium			S	Unknown	15 Mg, Q4wk		Not Reported
	Methotrexate Sodium			S	Unknown	12 Mg, Q4wk		Not Reported
	Methotrexate Sodium			S	Unknown	10 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	10 Mg, Weekly		Not Reported
	Methotrexate Sodium			S	Unknown	15mg, Weekly		Not Reported
	Methotrexate Sodium			S	Unknown	17.5 Mg, Weekly		Not Reported

Incomplete; Therapeutic Response Decreased; Ulcer	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	12.5 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	12 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	15 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Q4wk	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	25 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Oral	12.5 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	12.5 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	70 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	12 Mg, Q4wk	Not Reported
	Methotrexate Sodium	S	Unknown	15 Mg, Q4wk	Not Reported
	Methotrexate Sodium	S	Unknown	15.5 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Mg, Q4wk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Q4wk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	12 Mg, Weekly	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported

Codeine	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	680 Mg, Monthly	Not Reported
Simponi	S	Unknown	360 Mg, Monthly	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
Leflunomide	S	Oral	20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Daily	Not Reported
Leflunomide	S		20 Mg, 5 Days Out Of 7	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	20 Unk, Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Every 2 Weeks	Not Reported
Humira	S	Subcutaneous	40 Mg,Unk	Not Reported
Humira	S	Unknown	40 Mg, Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 1x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Daily	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Actemra	S	Unknown	360 Mg, Monthly	Not Reported
Actemra	S	Unknown	680 Mg, (Every 4 Weeks)	Not Reported
Actemra	S	Unknown	2.68 Mg, Q4wk,	Not Reported
Actemra	S	Unknown	360 Mg, Qmo	Not Reported

Actemra	S	Unknown	680 Mg, Qmo	Not Reported
Actemra	S	Unknown	680 Mg, Monthly	Not Reported
Actemra	S	Unknown	680 Mg, Unk	Not Reported
Orencia	S	Unknown	760 Mg, Weekly	Not Reported
Orencia	S	Unknown	780 Mg, Weekly	Not Reported
Orencia	S	Unknown	760 Mg, Weekly	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Monthly	Not Reported
Myochrysine	S	Intramuscular	25 Mg, Weekly	Not Reported
Myochrysine	S	Parenteral	50 Mg, Monthly	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Cyclic (Once Every Two Weeks)	Not Reported
Myochrysine	S	Unknown	50 Mg, Monthly	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	Unk	Not Reported
Alendronate Sodium	S	Unknown	Unk	Not Reported
Alendronate Sodium	S	Unknown	70 Mg, Weekly	Not Reported
Tocilizumab	S	Unknown	380 Mg, Unk	Not Reported
Tocilizumab	S	Unknown	360 Mg, Unk	Not Reported
Tocilizumab	S	Unknown	680 Mg, 1 Every 4 Week	Not Reported
Hydroxychloroquine	S	Oral	20 Mg, Unk	Not Reported
Hydroxychloroquine	S	Oral	200 Mg, 1x/Day	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported

Alendronic Acid	S	Unknown	70 Mg, Weekly	Not Reported
Rituximab	S	Unknown	1000 Mg, 2x/Day	Not Reported
Adalimumab	S	Subcutaneous	40 Mg, Q2wk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Unknown	70 Mg, Weekly	Not Reported
Prednisone	C	Unknown	10 Mg, 1x/Day	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	10 Mg, (Every 2 Hours)	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	10 Mg, (Every 2 Hours)	Not Reported
Prednisone	C		10 Mg, Unk	Not Reported
Cyclosporin	C	Unknown	150 Mg, Qd	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Prednisolone	C		Unk	Not Reported
Alendronate	C	Unknown	Unk	Not Reported
Alendronate	C	Unknown	70 Mg, Weekly	Not Reported
Alendronate	C	Unknown	70 Mg, Weekly	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16211394	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-020276		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling	Meloxicam			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	160 Milligram, Every Week		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Humira	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Mobicox	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Depo Medrol	C	Intra-articular	80 Milligram	Not Reported
	Depo Medrol	C	Intramuscular	80 Milligram, Once A Day	Not Reported
	Diclofenac	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Oral	Unk	Not Reported
	Plaquenil	C	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Two Times A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16216662	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-020655		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis;	Risedronate			S	Unknown	35 Milligram, Every Week		Aurobindo
	Risedronate			S	Unknown	16.35 Milligram, 1 Every 2 Weeks		Aurobindo
	Risedronate Tablet			S	Oral	35 Milligram, 1 Every 1 Week		Aurobindo
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actonel			S	Unknown	35 Milligram, 1 Every 1 Week		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported

Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Apo-Leflunomide	S	Unknown	20 Milligram, Cyclical	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, Once A Day	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, One Every One Hour	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Unknown	40 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram, 1 Every Two Weeks	Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram, Once A Day	Not Reported
	Hydroxychloroquine	S	Unknown	Unk, Once A Day	Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram, Once A Day	Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram, One Every One Hour	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Two Times A Day	Not Reported
	Hydroxychloroquine	S	Unknown	Unk, 1 Every 1 Week	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Once A Day	Not Reported
	Leflunomide	S	Oral	20 Milligram, Once A Day	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil	S	Oral	300 Milligram, Once A Day	Not Reported
	Plaquenil	S	Unknown	300 Milligram, Once A Day	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not	35 Milligram, Unk	Not Reported

			otherwise specified)			
	Rituxan	S	Intravenous (not otherwise specified)	1 Gram, Cyclical		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Xeljanz	C	Oral	5 Milligram, Two Times A Day		Not Reported
	Risedronate	C	Unknown	35 Milligram, Every Week		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16227903	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA020634			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Thyroxine Decreased; Treatment Failure; Vomiting	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	25 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Celebrex			S		Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	1 Dose		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

Otezla	S	Unknown	Unk	Not Reported
Cosentyx	S	Unknown	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Leflunomide	S		Unk	Not Reported
Desoximetasone	S		Unk	Not Reported
Humira	S		Unk	Not Reported
Methadone	S		Unk	Not Reported
Rampril	S		Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Estrogel	C	Unknown	0.6 %, Three Times A Day	Not Reported
Estrogel	C	Unknown	1.0 Df Qd	Not Reported
Estradiol	C		Unk, Tid	Not Reported
Calcium	C		500 Milligram, Qd	Not Reported
Xalatan	C	Ophthalmic	50 Microgram, Qd (50 Mcg 0.005% 1 Drop)	Not Reported
Cosopt	C		Unk, 2x/Day	Not Reported
Furosemide	C	Unknown	40 Milligram, Qd	Not Reported
Valsartan	C	Unknown	320 Milligram, Qd	Not Reported
Vitamin D	C		10000 Unit, Weekly	Not Reported
Jamp K20	C		1500 Mg, 1x/Day	Not Reported
Zingiber Officinale	C	Oral	500 Mg, As Needed	Not Reported
Dorzolamide Hcl And Timolol Maleate	C	Unknown	Unk, 2x/Day	Not Reported
Ergocalciferol	C	Unknown	Unk, Weekly	Not Reported
Ergocalciferol	C	Unknown	Unk, Qd	Not Reported
Morphine	C	Unknown	Unk Unk, As Necessary	Not Reported
Potassium Chloride	C	Unknown	1500 Mg, 1x/Day (Qd)	Not Reported
Gravol Ginger	C	Oral	500 Milligram, As Needed	Not Reported
Baclofen	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16446297	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2822466-00		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Feeling Abnormal; Insomnia; Pain In Extremity; Peripheral Swelling; Pneumonia; Rheumatoid Factor Increased; Rheumatoid Nodule; Somnolence; Weight Increased	Humira			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Plaquenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16510049	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570129-00		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Pain; Spinal Compression Fracture; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16682901	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-22253		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Liver Function Test Increased; Off Label Use; Palpitations; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Cosentyx			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Otezla			S	Oral	Unknown		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Acetaminophen And Codeine			C	Unknown			Not Reported
	Acetaminophen And Codeine			C	Unknown	Unknown		Not Reported
	Acetaminophen And Codeine			C	Unknown	Unknown		Not Reported
	Amitriptyline Hydrochloride			C	Unknown	Unknown		Not Reported
	Aspirin			C	Unknown	Unknown		Not Reported
	Baclofen			C	Unknown	Unknown		Not Reported
	Betahistine Hydrochloride			C	Unknown	Unknown		Not Reported

Caffeine	C	Unknown	Unknown		Not Reported
Calcium	C	Unknown	Unknown		Not Reported
Clonidine	C	Unknown	Unknown		Not Reported
Clonidine Hydrochloride	C	Unknown	Unknown		Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	Unknown		Not Reported
Fluticasone Propionate	C	Unknown	Unknown		Not Reported
Folinic Acid	C	Unknown	Unknown		Not Reported
Gabapentin	C	Unknown	Unknown		Not Reported
Hydrochlorothiazide	C	Unknown	Unknown		Not Reported
Losartan	C	Unknown	Unknown		Not Reported
Metoprolol Tartrate	C	Unknown	Unknown		Not Reported
Mometasone Furoate	C	Unknown	Unknown		Not Reported
Naproxen	C	Unknown	Unknown		Not Reported
Naproxen	C	Unknown	Unknown		Not Reported
Tylenol With Codeine	C	Unknown	Unknown		Not Reported
Folic Acid	C	Unknown			Not Reported
Plaquenil	C	Unknown			Not Reported
Acetaminophen	C	Unknown	Unknown		Not Reported
Codeine	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16700535	EXPEDITED (15-DAY)		HO, LT, OT	CA-ABBVIE-19K-028-2885154-00		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated;	Humira			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Triamcinolone Acetonide			S	Intra-articular	Route: Suspension Intra-		Not Reported

Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Wheelchair User	Triamcinolone Acetonide	S	Articular	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S		Not Reported
	Apo-Naproxen	S	Unknown	Not Reported
	Apo-Naproxen	S		Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S		Not Reported
	Naproxen	S	Unknown	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Not Reported
	Tocilizumab	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Triamcinolone	S	Unknown	Not Reported
	Triamcinolone	S		Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S		Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Anakinra	S		Not Reported
	Prednisone	S	Oral	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S		Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Gammagard	S	Intravenous (not otherwise specified)	Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)	Not Reported
	Triamcinolone Hexacetonide	S	Other	Not Reported
	Triamcinolone Hexacetonide	S		Not Reported

Folic Acid		C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16820459	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3442			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Product Use Issue; Rheumatoid Arthritis; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16833020	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2933128-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Unknown	Powder For Solution Intravenous	Not Reported
	Rituximab	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Arava	C			Not Reported
	Plaquenil	C	Oral		Not Reported
	Prednisone	C			Not Reported
	Simponi	C			Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17144108	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-19K-163-2800982-00		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthma; Asthma; Chest Discomfort; Chest X-Ray Abnormal; Fall; Glaucoma; Joint Swelling; Macular Degeneration; Musculoskeletal Disorder; Musculoskeletal Pain; Nausea; Pneumonia; Pyrexia; Respiratory Tract Infection Bacterial; Retinal Toxicity; Rib Fracture; Therapeutic Response Shortened; Wheelchair User; White Blood Cell Count Increased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Citrate Free		Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Iron			C	Unknown			Not Reported
	Folic			C	Unknown			Not Reported
	Eliquis			C				Not Reported
	Prilosec			C				Not Reported
	Zantac			C				Not Reported
	Losartan			C				Not Reported
	Flexeril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17153987	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA027344			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Morphine Sulfate			S	Unknown	Unk		Not Reported
	Morphine Hydrochloride			S	Unknown	Unk		Not Reported
	Cefixime			S	Unknown	Unk		Not Reported
	Imuran [Azathioprine]			S	Oral	100 Milligram		Not Reported
	Nifedipine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rivotril			S	Unknown	Unk		Not Reported
	Zantac			S	Unknown	Unk		Not Reported
	Zopiclone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17324085	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005924		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Anakinra	S	Unknown		Not Reported
	Anakinra	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Ilaris	S	Subcutaneous		Not Reported
	Ilaris	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17439290	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011929		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Toxic Skin Eruption	Coumadine			S	Oral	Unk		Bristol Myers Squibb
	Innohep			S	Oral	Unk		Not Reported
	Omnipaque			S	Intravenous (not otherwise specified)	55 Milliliter		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Kardegic			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17530620	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021584			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Off Label Use; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17549765	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2020-013114		29 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Drug Ineffective; Transient Ischaemic Attack; Treatment Failure	Atorvastatin			S	Unknown	Unk		Not Reported
	Clopidogrel			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported
	Apixaban			S	Unknown	Unk		Not Reported
	Rivaroxaban			S	Unknown	Unk,6 Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17563119	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022177		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Endocervical			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown	2 Dosage Form, Qd		Not Reported
	Ergocalciferol			C	Unknown	Unk, Qwk		Not Reported
	Estradiol			C	Unknown			Not Reported

Estrogel	C	Unknown	1 Dosage Form, Qd		Not Reported
Furosemide	C	Unknown	40 Milligram, Qd		Not Reported
Morphine	C	Unknown			Not Reported
Potassium Chloride	C	Unknown	1500 Milligram, Qd		Not Reported
Valsartan	C	Unknown	320 Milligram, Qd		Not Reported
Xalatan	C	Ophthalmic	50 Microgram, Qd		Not Reported
Zingiber Officinale	C	Oral	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17563205	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022138			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Kevzara			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Aluminum Acetate			C	Unknown			Not Reported
	Atacand			C	Unknown			Not Reported
	Benzethonium Chloride			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydrodiuril			C	Unknown			Not Reported
	Neurontin			C	Unknown	600 Milligram, 3 Every 1 Day		Not Reported
	Premarin			C	Unknown			Not Reported

	Tylenol		C	Unknown	650 Milligram, 2 Every 1 Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17563481	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566876		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Pyrexia; Rheumatoid Arthritis; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	Solution		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C				Not Reported
	Simponi			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17563513	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566890			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Acne Cystic; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Rituximab	S	Unknown		Not Reported
	Anakinra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral	Solution	Not Reported
	Orencia	S	Unknown		Not Reported
	Vioxx	S	Unknown		Not Reported
	Naproxen	S	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17563528	EXPEDITED (15-DAY)		HO, LT, OT	PT-ACCORD-176291		50 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Tamponade; Cardiogenic Shock; Cardiomegaly; Concomitant Disease Aggravated; Dyspnoea Exertional; Dyspnoea Paroxysmal Nocturnal; Electrocardiogram Qrs Complex Abnormal; Heart Sounds Abnormal; Oedema Peripheral; Pericardial Drainage; Pericardial Effusion; Pericardiotomy; Pleural	Mycophenolic Acid			S	Unknown	2.5 G, Qd		Accord
	Bosentan			S	Oral	250 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	5 Mg, Qd		Not Reported
	Remodulin Sq			S	Subcutaneous	0.046 Mg, Q1hour		Not Reported
	Riociguat			C	Unknown	6 Mg, Qd		Not Reported

Effusion; Prohormone
Brain Natriuretic Peptide
Increased; Rales; Serositis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17563805	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022560			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Prednisone			C	Unknown	2 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17563950	EXPEDITED (15-DAY)		OT	CA-ROCHE-2571269			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Simponi	C	Subcutaneous	Not Reported
Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17564021	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202003001710			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Abdominal Tenderness; Chest Pain; Cough; Decreased Appetite; Dyspnoea; Herpes Simplex Hepatitis; Lethargy; Lymphopenia; Musculoskeletal Chest Pain; Nausea; Somnolence; Thrombocytopenia	Hydroxychloroquine			S	Unknown	200 Mg, Bid, Tablet		Concordia
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Metronidazole			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17564032	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP008890			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Intolerance; Maculopathy; Pneumonia; Product Use Issue; Visual Impairment	Leflunomide			S	Oral	10 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Methotrexate			C	Subcutaneous	20 Mg, Unk		Not Reported
	Sulfasalazine			C	Unknown	500 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17564060	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573629-00		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pancreatitis; Product Use Issue	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Amitriptyline			C				Not Reported
	Hydromorph Contin			C				Not Reported
	Lyrica			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17564141	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1432			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Hepatitis B Reactivation; Inflammation; Malaise; Stomatitis; Weight Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17564207	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022599			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported

Consciousness; Mobility Decreased	Anakinra		S	Unknown	Not Reported
	Arava		S	Oral	Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous drip	Not Reported
	Simponi		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17564413	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566946			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17564456	EXPEDITED (15-DAY)		OT	CA-SA-2020SA067248			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Abdominal Pain; Diarrhoea; Diarrhoea; Nausea; Renal Failure	Leflunomide		S		20 Mg, Qd	Sanofi
	Plaquenil		S		400 Mg, Qd	Sanofi
	Methotrexate		S	Unknown	20 Mg, Qw	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17565635	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022535		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Orencia			S	Unknown	200 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Unk		Not Reported
	Prednisone			S	Unknown	20 Nanogram		Not Reported
	Rituximab			S	Intravenous drip	2 Gram		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	500 Unk		Not Reported
	Risedronate Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17566118	EXPEDITED (15-DAY)		DS	CA-AUROBINDO-AUR-APL-2019-095261		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood	Alendronic Acid			S	Unknown	70 Milligram, 4 Every 1 Week		Aurobindo
	Apo-Alendronate			S	Unknown	Unk		Not Reported

Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Ibuprofen	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Oral	500 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Methotrexate	S	Oral	10 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Subcutaneous	12 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Subcutaneous	12.5 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Subcutaneous	17.5 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Subcutaneous	70 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Unknown	12 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Unknown	12.5 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Unknown	17.5 Milligram,Four In One Week	Not Reported
	Apo-Methotrexate	S	Unknown	12 Milligram,Four In One Week	Not Reported
	Apo-Methotrexate	S	Unknown	10 Milligram, Four In One Week	Not Reported
	Apo-Methotrexate	S	Unknown	12.5 Milligram,Four In One Week	Not Reported
	Apremilast	S	Unknown	60 Milligram, Two Times A Day	Not Reported
	Apremilast	S			Not Reported
	Apremilast	S			Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Milligram,Two Every One Week	Not Reported

Enbrel	S	Unknown	25 Milligram	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Ibuprofen	S	Oral	600 Milligram	Not Reported
Ibuprofen	S	Unknown	600 Milligram, Once A Day	Not Reported
Ibuprofen	S	Unknown	Unk, Once A Day	Not Reported
Infliximab	S	Oral	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Motrin	S	Oral	600 Mg, Qd	Not Reported
Motrin	S	Oral	Unk Unk, Qd	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S			Not Reported
Otezla	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Two Times A Day	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	1000 Mg, Bid	Not Reported
Sulfasalazine	S	Endocervical	Unk	Not Reported
Tocilizumab	S	Unknown	360 Milligram,One Every Month	Not Reported
Tocilizumab	S	Unknown	680 Milligram,One Every Four Week	Not Reported
Alendronate	C	Unknown	70 Mg, Q.Wk.	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Ciclosporin	C	Unknown	Unk	Not Reported
Colchicine	C	Oral	Unk	Not Reported

Dexilant	C	Unknown	Unk	Not Reported
Febuxostat	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Humira	C	Unknown	40 Milligram	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram,Four Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, Four Every 1 Week	Not Reported
Methotrexate	S	Unknown	10 Milligram,Four Every 1 Week	Not Reported
Methotrexate	S	Unknown	12.5 Milligram,Four Every 1 Week	Not Reported
Methotrexate	S	Unknown	12 Milligram,Four Every 1 Week	Not Reported
Methotrexate	S	Unknown	70 Milligram, Every Week	Not Reported
Mogadon	C	Oral	5 Milligram	Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	20 Milligram	Not Reported
Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported
Tocilizumab	C	Unknown	680 Milligram	Not Reported
Tocilizumab	C	Unknown	360 Milligram	Not Reported
Uloric	C	Unknown	80 Milligram, Two Times A Day	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17566974	EXPEDITED (15-DAY)		OT	NVSC2020CA079201			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Eye Disorder; Off Label Use; Psoriasis; Rash; Rheumatoid Arthritis; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hidroxicloroquina			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Desvenlafaxine Succinate			C	Unknown	Unk		Not Reported
	Leflunomide			C	Oral	20 Mg, Qd		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Quetiapine Fumarate			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17567557	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022569		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Swelling; Nasopharyngitis; Off Label	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

Use; Rheumatoid Arthritis; Suicidal Ideation	Alendronate Sodium		C	Unknown	Not Reported
	Fosamax		C	Unknown	Not Reported
	Ibuprofen		C	Unknown	Not Reported
	Lisinopril		C	Unknown	Not Reported
	Vitamin D 3		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17567671	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA078923			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug-Induced Liver Injury; Off Label Use	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk (Solution)		Not Reported
	Stelara			S	Subcutaneous	Unk (Solution)		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17567912	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022607		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	160 Milligram, Qwk		Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Methotrexate	S	Unknown	Not Reported
	Mobicox	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17567934	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022780		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Feeling Abnormal; Insomnia; Pain In Extremity; Peripheral Swelling; Pneumonia; Rheumatoid Factor Increased; Rheumatoid Nodule; Somnolence; Weight Increased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17568087	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022579		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pancreatitis; Product Use Issue	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	25.0 Milligram		Not Reported
	Plaquenil S			S	Unknown	200.0 Milligram, Qwk		Not Reported
	Amitriptyline			C	Unknown			Not Reported
	Hydromorph Contin			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17568106	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022615		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation; Choking; Cough; Drug Ineffective; Drug Intolerance; Facial Pain; Fatigue; Fibromyalgia; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Insomnia; Joint Range Of Motion Decreased; Melanocytic Naevus; Nasal Discomfort; Nausea; Night Sweats; Oropharyngeal Discomfort; Pain; Pain In Extremity; Pain In Jaw; Peripheral Coldness; Rhinorrhoea; Skin Mass	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25.0 Milligram		Not Reported
	Xeljanz			S	Oral	5.0 Milligram 2 Every 1 Days		Not Reported
	Xeljanz			S	Oral	5.0 Milligram 1 Every 1 Days		Not Reported
	Morphine			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17568283	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA068487			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Drug Ineffective	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S	Oral	20 Mg		Sanofi
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	17.5 Mg		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17568289	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068881			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S		200 Mg, Bid		Sanofi
	Methotrexate			S		20 Mg, Qw		Not Reported
	Leflunomide			S		20 Mg, Qd		Sanofi
	Actemra			S				Not Reported
	Enbrel			S		25 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	15622307	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557499-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Bupropion			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	15624381	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556781-00		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira	S	Subcutaneous	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Meloxicam	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C		Not Reported
	Prednisolone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	15625734	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557153-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Apo Prednison	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	15663999	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570464-00		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Joint Swelling; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Itravenous		Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)		
	Rituxan	S	Intravenous (not otherwise specified)	Solution Ntravenous	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Rituximab	S			Not Reported
	Lyrica	C	Oral		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	15683294	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573840-00		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure	Orencia	S	Unknown	Not Reported
	Mobicox	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil	C	Unknown	Not Reported
	Diclofenac	C		Not Reported
	Depo-Medrol	C	Intra-arterial	Not Reported
	Xeljanz	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Pantoprazole Magnesium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	16718423	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2892907-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	17563703	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3328160-00		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Headache; Pneumothorax	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Tylenol			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	17567968	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2020025732			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Drug Ineffective; Transient Ischaemic Attack; Treatment Failure	Clopidogrel			S	Unknown	Unk		Macleods
	Atorvastatin			S	Unknown	Unk		Not Reported
	Apixaban			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported
	Rivaroxaban			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	17572435	DIRECT					39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral	Hydroxychloroquine	Y		S			6 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	13186699	EXPEDITED (15-DAY)		OT	CA-ROCHE-1888735		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Rheumatoid Arthritis; Viral Upper Respiratory Tract Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported
	Hydroxychloroquine Sulfate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	14906435	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1678150-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tylenol			S	Unknown	Dosage Maintained		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Meloxicam			C	Unknown			Not Reported
	Synthroid			C				Not Reported
	Tylenol No. 3			C				Not Reported

Celebrex	C		Not Reported
Acetaminophen And Codeine Phosphate	C		Not Reported
Hydromorphone Hcl	C		Not Reported
Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	14921809	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043962		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Gold			S	Unknown			Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Humira			S	Unknown	200 Milligram, Bid		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	40 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported
	Remicade			S	Unknown	200 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported

Acetaminophen	C	Unknown	Unk	Not Reported
Anakinra	C	Unknown	100 Mg, Unk	Not Reported
Ativan	C	Unknown	1 Gram, Qd	Not Reported
Ativan	C	Unknown	1 Milligram	Not Reported
Codeine	C	Unknown		Not Reported
Desoximetasone	C	Oral	Unk	Not Reported
Desoximetasone	C	Intramuscular	Unk	Not Reported
Desoximetasone	C	Intra-articular	Unk	Not Reported
Dexamethasone	C	Unknown		Not Reported
Dilaudid	C	Unknown	4 Milligram, Qid	Not Reported
Dilaudid	C	Unknown	4 Milligram, Qd	Not Reported
Diphenhydramine	C	Unknown		Not Reported
Enablex [Darifenacin]	C	Unknown		Not Reported
Enablex [Darifenacin]	C	Unknown		Not Reported
Hydromorphone	C	Unknown		Not Reported
Kadian	C	Unknown		Not Reported
Kenalog [Triamcinolone Acetonide]	C	Intra-articular	40 Mg, Unk	Not Reported
Lasix [Furosemide]	C	Unknown	40 Milligram, Tid	Not Reported
Loperamide	C	Unknown	2 Milligram, Bid	Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown		Not Reported
Omnaris	C	Unknown		Not Reported
Oxyneo	C	Unknown		Not Reported
Pantoprazole Sodium	C	Unknown		Not Reported
Restasis	C	Unknown		Not Reported
Synthroid	C	Unknown		Not Reported
Trimethoprim	C	Unknown		Not Reported
Urispas	C	Unknown	200 Milligram	Not Reported
Vagifem	C	Vaginal		Not Reported
Dyclonine Hydrochloride	C	Unknown	Unk	Not Reported

	Benadryl Cold	C	Unknown		Not Reported
	Diphenhydramine Hydrochloride	C	Unknown	Unk, Prn	Not Reported
	Morphine Sulphate	C	Unknown		Not Reported
	Plantago Ovata	C	Unknown		Not Reported
	Rituximab	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	15328456	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175439			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	15683363	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2574500-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatic Disorder; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Aspirin	C		Not Reported
	Cymbalta	C		Not Reported
	Hydromorphone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	17530404	EXPEDITED (15-DAY)		OT	NVSC2020CA070217			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	17533813	EXPEDITED (15-DAY)		OT	NVSC2020CA069732		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	1 Df		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	50 Mg		Not Reported
	Zingiber Officinale			C	Oral	500 Mg		Not Reported
	Zingiber Officinale			C	Unknown	500 Mg		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Xalatan			C	Ophthalmic	50 Mg, Qd		Not Reported
	Valsartan			C	Unknown	320 Mg, Qd		Not Reported
	Potassium Chloride			C	Unknown	1500 Mg, Qd		Not Reported
	Morphine			C	Unknown	Unk		Not Reported

	Jamp K20	C	Unknown	1500 Mg, Qd	Not Reported
	Gravol	C	Unknown	500 Mg	Not Reported
	Furosemide	C	Unknown	40 Mg, Qd	Not Reported
	Estrogel	C	Unknown	1 Df, Qd	Not Reported
	Estrogel	C	Unknown	0.6 % Tid	Not Reported
	Estradiol	C	Unknown	0.6 % Tid	Not Reported
	Ergocalciferol	C	Unknown	Unk Unk, Qw	Not Reported
	Ergocalciferol	C	Unknown	Unk Unk, Qw	Not Reported
	Ergocalciferol	C	Unknown	Unk Unk, Qd	Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown	Unk Unk, Bid	Not Reported
	Calcium	C	Unknown	500 Mg, Qd	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Tofacitinib Citrate	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	17542710	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA071289		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

Simponi	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	500 Mg, Bid		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Naprosyn	C	Unknown			Not Reported
Erythromycine	C	Unknown	Unk		Not Reported
Morphine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	17545270	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-020929			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Somnolence; Visual Impairment	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Acetaminophen			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	2000 Milligram		Not Reported
	Tylenol			S	Unknown			Not Reported
	Synthroid			C	Unknown	Unk		Not Reported

	Meloxicam	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	25 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	17569409	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022556		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	680 Milligram		Not Reported
	Actemra			S	Unknown	360 Milligram 1 Every 1 Months		Not Reported
	Alendronate			S	Unknown	70 Milligram 1 Every 1 Weeks		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Unknown	12.0 Milligram 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Unknown	10.0 Milligram 1 Every 1 Weeks		Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown	1000 Milligram 2 Every 1 Days		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram 1 Every 1		Not Reported

				Weeks	
	Methotrexate	S	Subcutaneous	15.0 Milligram 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Oral	10 Milligram 1 Every 1 Weeks	Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	11865597	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2012292491		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S				Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day (Q12h)		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	10 Mg, Daily (2 In 1 Day)		Pfizer
	Xeljanz			S		12.5 Mg, Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 1x/Day Qd (1 Every 1 Day)		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Aleve	S	Unknown	Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Apo-Leflunomide	S	Oral	5 Mg, 2x/Day (Q12h)	Not Reported
Apo-Leflunomide	S	Oral	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Naproxen	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Cosentyx	S	Unknown	Unk	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S		Unk	Not Reported
Hydroxychloroquine Sulfate	S		40 Mg, Unk	Not Reported
Apo-Hydroxyquine	S		400 Milligram	Not Reported
Prednisone Acetate	S	Unknown	Unk	Not Reported
Naproxen	S		Unk	Not Reported
Leflunomide	S	Unknown	Unk Unk, Cyclical (1 Every Two Days)	Not Reported
Leflunomide	S	Unknown	Unk Unk, Bid	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	400 Mg, Unk	Not Reported
Folic Acid	C	Subcutaneous	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported

	Hcq	C		Unk	Not Reported
	Acetaminophen And Codeine	C	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	2 Df, Qd	Not Reported
	Insulin	C	Unknown	Unk	Not Reported
	Metformin	C	Unknown	2 Dosage Form, Bid	Not Reported
	Tylenol [Paracetamol]	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	20 Milligram	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	12769492	EXPEDITED (15-DAY)		CA, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076352			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Drug Ineffective; Drug Intolerance; Insomnia; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis	Orencia			S	Endocervical	Unk		Bristol Myers Squibb
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	Unk Unk, 2 Times/Wk		Not Reported
	Enbrel			S	Unknown	Unk, Q2wk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Naproxen			S	Oral	500 Mg, Bid		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Vioxx			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Naprosyn [Naproxen]			S	Oral	500 Milligram, Bid		Not Reported

Naprosyn [Naproxen]	S	Unknown	500 Milligram, 2 Times/Wk		Not Reported
Naproxen Sodium	S	Oral	500.0 Milligram, Bid		Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Leflunomide	S	Unknown	20 Milligram		Not Reported
Actemra	S	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Leflunomide	C	Unknown	10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	13147266	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005239		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Ill-Defined Disorder; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Off Label Use; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	200 Milligram, Bid		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Toradol			S	Unknown			Not Reported
	Celecoxib			S	Oral	200 Milligram, Bid		Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Tramadol			C	Unknown	100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	13251292	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP006546		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Hernia; Joint Destruction; Nausea; Rheumatoid Arthritis; Stoma Complication	Hydroxychloroquine			S	Oral	400 Mg, Bid		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Oral	200 Mg, Bid		Not Reported
	Methotrexate Sodium			S	Subcutaneous	0.8 Ml, Q.Wk.		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	14235040	EXPEDITED (15-DAY)		DE, OT	CA-APOTEX-2017AP021690		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Drug Hypersensitivity; Drug Ineffective; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Adalimumab			S	Subcutaneous	40 Mg, Q.Wk.		Not Reported
	Adalimumab			S				Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	22.5 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Qid		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Plaquenil /00072602/			C	Unknown	Unk		Not Reported

	Xeljanz	C	Oral	50 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	14238496	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021706			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Feeding Disorder; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Varenicline Tartrate			S	Oral	1 Df, Qd		Not Reported
	Varenicline Tartrate			S				Not Reported
	Acetaminophen W/Oxycodone Hydrochloride			C	Unknown	Unk		Not Reported
	Esomeprazole Magnesium W/Naproxen			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Rosuvastatin Calcium			C	Unknown	Unk		Not Reported
	Tofacitinib Citrate			C	Unknown	Unk		Not Reported
	Valtrex			C	Unknown	Unk		Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown	Unk		Not Reported

U.S. FOOD & DRUG ADMINISTRATION

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	14239514	EXPEDITED (15-DAY)		HO, OT	CA-PURDUE PHARMA-CAN-2016-0006553		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Skin Lesion; Sleep Disorder; Treatment Failure	Oxycontin			S	Unknown	Unk		Purdue
	Actemra			S	Intravenous (not otherwise specified)	488 Mg, Monthly		Not Reported
	Arava			S	Oral	20 Mg, Daily		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Weekly		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Gabapentin			S	Oral	100 Mg, Bid		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk Unk, Weekly		Not Reported
	Myochrysine			S	Intramuscular	50 Mg, 1 Every 3 Weeks		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Monthly		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, 1 Every 3 Weeks		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Daily		Not Reported
	Sulfasalasin			S	Oral	2.5 G, Daily		Not Reported
	Acetaminophen W/Oxycodone			C		1 Df, Prn		Not Reported
	Aclasta			C	Intravenous (not otherwise specified)	750 Mg, Monthly		Not Reported
	Actonel			C	Unknown	36 Mg, Weekly		Not Reported
	Ascorbic Acid			C	Unknown	Unk		Not Reported
	Biotin			C	Unknown	Unk		Not Reported
	Calcium			C	Unknown	Unk		Not Reported
	Tocopherol			C	Unknown	1200 Mg, Bid		Not Reported
	Tocopherol			C	Unknown	Unk		Not Reported
	Diphenoxylate Hydrochloride			C	Unknown	2.5 Mg, Daily		Not Reported

Diphenoxylate Hydrochloride	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	400 Iu, Daily	Not Reported
Ergocalciferol	C	Unknown	Unk Unk, Daily	Not Reported
Esomeprazole Magnesium	C	Unknown	40 Mg, Bid	Not Reported
Ferrous Gluconate	C	Unknown	300 Mg, Daily	Not Reported
Loperamide Hcl	C	Unknown	2.5 Mg, Unk	Not Reported
Nasonex	C	Nasal	2 Df, Bid	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Mg, Unk	Not Reported
Omega-3 Fatty Acids	C	Unknown	1200 Mg, Bid	Not Reported
Pantoprazole	C	Unknown	40 Mg, Daily	Not Reported
Prednisone	C	Unknown	5 Mg, Daily	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Sodium	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Trazodone Hydrochloride	C	Oral	50 Mg, Daily	Not Reported
Tylenol /00020001/	C	Oral	1000 Mg, Daily	Not Reported
Vitamin A /00056001/	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Vitamin B12 /00056201/	C	Unknown	Unk	Not Reported
Ferrous Fumarate	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Sodium Ascorbate	C	Unknown	Unk	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported
Vitamin C /00008001/	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	14757583	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009592			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Intolerance; Impaired Work Ability; Middle Insomnia; Rheumatoid Arthritis; Rheumatoid Nodule; Synovitis; White Blood Cell Count Decreased	Hydroxychloroquine	S	Unknown	Unk		Apotex
	Leflunomide	S	Unknown	Unk		Apotex
	Penicillin	S	Unknown	Unk		Apotex
	Acetylsalicylic Acid	S	Unknown	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Plaquenil /00072602/	S	Unknown	Unk		Not Reported
	Aspirin /00002701/	S	Unknown	Unk		Not Reported
	Penicillin G /00000901/	S	Unknown	Unk		Not Reported
	Penicillin G Potassium	S	Unknown	Unk		Not Reported
	Penicillin G Procaine	S	Unknown	Unk		Not Reported
	Pregabalin	C	Unknown	Unk		Not Reported
	Tylenol /00020001/	C	Unknown	Unk		Not Reported
	Acetaminophen	C	Unknown	Unk		Not Reported
	Acetaminophen And Codeine Phosphate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	15619609	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555410-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	11 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	15623842	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557025-00		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Mobility Decreased; Product Dose Omission; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Toe Amputation; Victim Of Crime	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Ophthalmic			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Restasis			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Vitamins Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	15629783	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2557408-00		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Malaise; Mood Swings; Musculoskeletal Stiffness; Nausea; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event; Vomiting	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Indometacin			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	Cymbalta			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	16357705	EXPEDITED (15-DAY)			CA-ORION CORPORATION ORION PHARMA-TREX2019-1532			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hyperhidrosis; Inappropriate Schedule Of Product Administration; Nausea; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Estradot			S	Transdermal			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	16473931	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1994		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Inflammation; Joint Stiffness; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Kevzara			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Humira	S	Unknown	Not Reported
Humira	S	Unknown	Not Reported
Humira	S	Unknown	Not Reported
Simponi	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Subcutaneous	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Subcutaneous	Not Reported
Cimzia	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Abatacept	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Plaquenil	S	Oral	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Adalimumab	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Sarilumab	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Tofacitinib Citrate	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rabeprazole Sodium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	16857402	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2574079-00		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Contraindicated Product Administered; Rash; Treatment Failure; Urticaria	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17529190	EXPEDITED (15-DAY)		OT	NVSC2020AU065740			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Eye Movement Disorder; Mobility Decreased; Scleroderma	Tacrolimus			S	Unknown	Unk		Novartis
	Prednisone			S	Unknown	10 Mg, Unknown		Not Reported
	Prednisone			S	Unknown	Up To 50 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	0.25 Mg/Kg, Unknown		Not Reported
	Prednisolone			S	Unknown	1 Mg/Kg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569440	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023131			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569450	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023149			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Neutropenia	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Endocervical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569480	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003001670			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatic Enzyme Increased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	1000 Mg, Bid		Not Reported
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Gliclazide			C		Unk		Not Reported
	Vimovo			C		Unk		Not Reported
	Rabeprazole			C		Unk		Not Reported
	Mr			C		Unk		Not Reported
	Metformin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569650	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022575		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	680 Milligram, Q4wk		Not Reported
	Actemra			S	Unknown	360 Milligram, Qwk		Not Reported
	Alendronate			S	Unknown	70 Milligram, Qwk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, Qwk		Not Reported
	Humira			S	Unknown	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	12 Milligram		Not Reported

Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Methotrexate		S	Subcutaneous	12.5 Milligram	Not Reported
	Methotrexate		S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Methotrexate		S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate		S	Unknown	12.5 Milligram, Qwk	Not Reported
	Methotrexate		S	Unknown	10 Milligram, Qwk	Not Reported
	Methotrexate		S	Oral	10 Milligram, Qwk	Not Reported
	Myochrysine		S	Intramuscular	50 Milligram, Qmo	Not Reported
	Rituximab		S	Intravenous drip	1000 Milligram, Bid	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Xeljanz		C	Unknown	Unk	Not Reported
	Prednisone		C	Unknown	Unk	Not Reported
	Ciclosporin		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569669	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023123			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Orencia			S	Endocervical			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown	2 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569671	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022648		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Rash; Treatment Failure; Urticaria	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569754	EXPEDITED (15-DAY)		HO	CA-ROCHE-2565726		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sulfasalazine	S	Unknown	Not Reported
	Naprosyn [Naproxen]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569843	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022714		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, Qmo		Not Reported
	Arava			S	Intravenous (not otherwise specified)	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Gabapentin			S	Unknown	100 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Qwk		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, Q3wk		Not Reported
	Oxycontin			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	2.5 Gram, Qd		Not Reported
	Aclasta			C	Intravenous (not otherwise specified)	750 Milligram, Qmo		Not Reported
	Ascorbic Acid			C	Unknown	Unk		Not Reported
	Biotin			C	Unknown	Unk		Not Reported
	D-Alpha Tocopherol			C	Unknown	1200 Milligram, Bid		Not Reported
	Diphenoxylate Hydrochloride			C	Unknown	2.5 Milligram, Qd		Not Reported
	Ergocalciferol			C	Unknown	400 International Unit, Qd		Not Reported
	Esomeprazole			C	Unknown	40 Milligram, Bid		Not Reported
	Ferrous Fumarate			C	Unknown	300 Milligram		Not Reported

Folic Acid	C	Unknown	Unk	Not Reported
Hydroxocobalamin	C	Unknown	Unk	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Milligram	Not Reported
Nasonex	C	Unknown	2 Dosage Form, Bid	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Nortriptyline Hydrochloride	C	Oral	40 Milligram, Qd	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Milligram	Not Reported
Prednisone	C	Unknown	5 Gbq 1 Every 1 Day	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Risedronate Sodium	C	Unknown	36 Milligram, Qd	Not Reported
Sodium Ascorbate	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Qd	Not Reported
Tylenol	C	Unknown	1000 Milligram, Qd	Not Reported
Vitamin A [Retinol]	C	Unknown	Unk	Not Reported
Vitamin C [Ascorbic Acid]	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569878	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2020-1453			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Drug Ineffective	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

Arava	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569879	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1451			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Atorvastatin Calcium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Alprazolam			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Naprosyn			C	Unknown			Not Reported
	Pantoloc			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570139	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201611-005804			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis;	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Unk		Concordia
	Arava			S	Oral	10 Mg, Qd		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Not Reported
	Gold			S	Unknown	Unk		Not Reported

Sleep Disorder Due To General Medical Condition, Insomnia Type	Humira	S	Subcutaneous	Every Other Week	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Weekly	Not Reported
	Methotrexate	S	Unknown	20 Mg (Tablet)	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Prednisone	S	Endocervical	20 Mg, Qd	Not Reported
	Prednisone	S	Endocervical	20 Mg, Qd	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	2 G,Qcy; Iv Nos	Not Reported
	Rituxan	S	Unknown	2 Unk, Qcy; Unknown	Not Reported
	Sulfasalazine	S	Oral	500 Mg, Bid	Not Reported
	Sulfasalazine	S	Unknown	1000 Mg, Bid	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	2 G, Q6m; Iv Nos	Not Reported
	Etanercept	S		50 Mg, Weekly	Not Reported
	Methotrexate	C			Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570142	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202001000092			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Dry Eye; Dry Mouth; Fatigue; Finger Deformity; Impaired Driving Ability; Macular Degeneration; Pain In Extremity; Rheumatoid Arthritis; Rheumatoid Nodule; Somnolence	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Unk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Levothyroxin			C		Unk		Not Reported
	Raloxifene			C		Unk		Not Reported
	Lidoderm			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570259	EXPEDITED (15-DAY)		LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023559			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Q2wk		Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous	Unk Unk, Qd		Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	3 Milligram, Bid		Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram, Qwk		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral	Unk Unk, Qd		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Oral	250 Milligram, Qd		Not Reported
	Triamcinolone			S	Intra-articular			Not Reported
	Triamcinolone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570302	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068781			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Interstitial Lung Disease; Rash	Leflunomide		S		10 Mg	Sanofi
	Plaquenil		S	Oral	200 Mg, Q12h	Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570308	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068804			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease	Leflunomide			S	Unknown	Unk		Sanofi
	Plaquenil			S	Unknown	400 Mg		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570311	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068793			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Hepatotoxicity; Rash; Treatment Failure	Leflunomide			S				Sanofi
	Hydroxychloroquine Sulfate			S		1 Df		Sanofi
	Adalimumab			S	Subcutaneous			Not Reported
	Azathioprine			S		1 Df		Not Reported
	Orencia			S	Subcutaneous	125 Df, Qw		Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570367	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023442		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine Sulphate	S	Unknown		Not Reported
	Hydroxychloroquine Sulphate	S	Unknown		Not Reported
	Ilaris	S	Subcutaneous		Not Reported
	Ilaris	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Other		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570370	EXPEDITED (15-DAY)		HO, OT	CN-LUPIN PHARMACEUTICALS INC.-2020-01473		52 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nocardiosis	Hydroxychloroquine			S	Unknown	0.2 Gram, Bid		Lupin

Prednisone	S	Unknown	60 Milligram, Qd		Not Reported
Prednisone	S	Unknown	50 Milligram, Qd		Not Reported
Prednisone	S	Unknown	20 Milligram, Qd In 2 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570449	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2500975-00		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation; Choking; Cough; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Facial Pain; Fatigue; Fibromyalgia; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Insomnia; Joint Range Of Motion Decreased; Lipoma; Melanocytic Naevus; Nasal Discomfort; Nausea; Night Sweats; Oropharyngeal Discomfort; Osteoporosis; Pain; Pain In Extremity; Pain In Jaw; Peripheral Coldness; Platelet Count Decreased; Rhinorrhoea; Skin Mass	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Synthetic Morphine			C	Unknown	Unknown Dose 1 Or 2		Not Reported
	Tylenol			C		Unknown Hs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570489	EXPEDITED (15-DAY)		OT	CA-ROCHE-2571132		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Drug Ineffective; Joint Swelling; Malaise; Mobility Decreased; Musculoskeletal Stiffness; Osteomyelitis; Pain; Rheumatoid Arthritis; Rheumatoid Lung; Rheumatoid Nodule; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz Xr			C	Oral			Not Reported
	Xeljanz Xr			C	Unknown			Not Reported
	Xeljanz Xr			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570607	EXPEDITED (15-DAY)		OT	NVSC2020CA077910		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	6.78 Mg/Kg (Cumulative Dose 1.24 Kg)		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570792	EXPEDITED (15-DAY)		OT	NVSC2020CA079412		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Synovitis	Cosentyx	S	Unknown	Unk		Novartis
	Methotrexate	S	Unknown	Unk		Not Reported
	Cimzia	S	Subcutaneous	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Otezla	S	Oral	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Remicaide	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Stelara	S	Subcutaneous	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Leflunomide	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17571152	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020118213			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate Sodium			S	Oral			Pfizer
	Methotrexate Sodium			S	Other	Unk		Pfizer
	Enbrel			S	Unknown			Pfizer
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17571244	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020118892			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate Sodium			S		20 Mg		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		300 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17571456	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA079635		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Malaise; Osteoarthritis; Pain; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Voltaren Sr			S	Oral	75 Mg, Bid		Novartis
	Apo Diclo			S	Oral	75 Mg, Bid		Not Reported
	Apo Lisinopril			S	Oral			Not Reported
	Diclofenac			S	Oral	75 Mg, Bid		Not Reported
	Diclofenac			S	Oral	75 Mg, Bid		Not Reported
	Diclofenac Potassium			S	Oral	75 Mg, Prn		Novartis
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Qd		Not Reported
	Lisinopril			S	Unknown			Not Reported
	Lisinopril Dihydrate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Pantoprazol			S	Unknown			Not Reported
	Pantoprazol			S	Oral	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	2 G, Qd		Not Reported
	Synthroid			S	Oral			Not Reported
	Tecta			S	Oral			Not Reported

	Xeljanz	S	Oral	10 Mg, Qd	Not Reported
	Gold	C	Unknown		Not Reported
	Depo-Medrol	C	Intramuscular		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17572087	EXPEDITED (15-DAY)		OT	CA-SA-2020SA069054			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Inflammation; Rheumatoid Arthritis	Leflunomide			S	Unknown	Unk		Sanofi
	Plaquenil			S	Unknown	Unk		Sanofi
	Etanercept			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17572198	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024000			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Ilaris	S	Intravenous (not otherwise specified)		Not Reported
	Ilaris	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ilaris	S	Subcutaneous		Not Reported
	Ilaris	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17572243	EXPEDITED (15-DAY)		OT	US-SA-2020SA071865			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium; Drug	Hydroxychloroquine			S				Sanofi
	Docetaxel			S				Sanofi

Interaction; Retinopathy; Visual Field Defect	Anastrozole	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17572378	EXPEDITED (15-DAY)		OT	NVSC2020CA079465			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug-Induced Liver Injury; Off Label Use	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573060	EXPEDITED (15-DAY)		HO, LT, OT	PT-MYLANLABS-2020M1029307			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Tamponade; Cardiogenic Shock; Serositis	Mycophenolate Mofetil			S	Unknown	2.5 Gram		Not Reported
	Bosentan			S	Unknown	250 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Mylan
	Prednisolone			S	Unknown	5 Milligram		Mylan
	Remodulin			S	Subcutaneous	0.046 Mg/H, Continuing		Mylan
	Riociguat			C	Unknown	6 Milligram		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573076	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA079709		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Off Label Use; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Disorder; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Naprosyn			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573103	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1031278		13 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Hydroxychloroquine			S	Unknown	For 6 Weeks		Not Reported
	Prednisone			S	Oral	1 Milligram/Kilogram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573142	EXPEDITED (15-DAY)		OT	NVSC2020CA079502		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Drug Ineffective; Eye Disorder; Gait Disturbance; Gait Inability; Joint Dislocation; Stomatitis	Voltaren	S	Unknown	Unk	Novartis
	Diclofenac Sodium	S	Unknown	Unk	Novartis
	Diclofenac	S	Unknown	Unk	Novartis
	Diclofenac Potassium	S	Unknown	Unk	Novartis
	Methotrexate	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Apo-Diclofenac	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Unknown	Unk	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573170	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023021		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk, Q2wk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk, Q6wk		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573206	EXPEDITED (15-DAY)		OT	NVSC2020CA079493		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Osteoarthritis; Pain; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Voltaren Sr			S	Unknown	75 Mg, Prn		Novartis
	Folic Acid			S	Unknown	Unk		Not Reported
	Lisinopril			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Plaquenil			S	Oral	200 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Qd		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Tecta			S	Oral	Unk		Not Reported
	Xeljanz			S	Unknown	5 Mg, Bid		Not Reported
	Depo-Medrol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573227	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023154			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Subcutaneous	1 Milligram		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Rituximab		S	Intravenous (not otherwise specified)	Unk			Not Reported
	Simponi		S	Subcutaneous				Not Reported
	Sulfasalazine		S	Unknown	Unk			Not Reported
	Topicort Lp		S	Topical	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573297	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023109		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	25 Milligram, Qwk		Not Reported
	Prednisone			C	Unknown	30 Milligram, Qd		Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573405	NON-EXPEDITED			NVSC2020US082232			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychotic Disorder	Hydroxychloroquine			S	Oral	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17581632	DIRECT					66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Purpura	Plaquenil			S	Oral			Not Reported
	Tirosint			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	13058057	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015766		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	13251448	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006660			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Apo-Hydroxyquine			S	Unknown			Apotex
	Apo-Hydroxyquine			S				Apotex
	Apo-Cyclosporine			S	Unknown			Apotex
	Apo-Cyclosporine			S				Apotex
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S				Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Cyclosporine			S				Apotex
	Azathioprine			S	Unknown	Unk		Apotex
	Azathioprine			S				Apotex
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported
	Actemra			S	Unknown	640 Mg, Q.Wk.		Not Reported
	Arava			S	Oral			Not Reported
	Arava			S				Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Q.Wk.		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Gold			S	Unknown			Not Reported
	Gold			S				Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.Wk.		Not Reported
	Humira			S	Unknown	400 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.Wk.		Not Reported
	Imuran /00001501/			S	Unknown			Not Reported

	Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S				Not Reported
	Plaquenil /00072602/	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Sulfasalazine	S				Not Reported
	Tocilizumab	S	Unknown	640 Mg, Q.Wk.		Not Reported
	Tocilizumab	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	14498265	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007254			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Off Label Use; Thyroid Disorder	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	15629234	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2558776-00		21 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Hospitalisation; Infection; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pneumonia; Rash; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Humira	S	Subcutaneous		Not Reported
	Acetaminophen	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral	Dose Decreased	Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	Single Use Pre Filled Syringe	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous drip		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Apo-Hydroxyquine	S	Oral		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Tylenol	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Intravenous Drip	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Apo-Acetaminophen	S	Unknown		Not Reported
	Doxycycline	S	Unknown		Not Reported
	Doxycycline Hyclate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Etanercept	S	Unknown		Not Reported

	Abatacept	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Acetaminophen/Codeine Phosphate	C	Unknown	Not Reported
	Meloxicam	C		Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Synthroid	C	Unknown	Not Reported
	Codeine Phosphate	C		Not Reported
	Hydromorphone Hydrochloride	C	Unknown	Not Reported
	Celebrex	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	15632850	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105426		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Q4wk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8.0 Milligram/Kilogram		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Xeljanz			C	Unknown	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	15689905	EXPEDITED (15-DAY)		HO, OT	CA-SAKK-2018SA324553AA		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Nausea; Obesity; Septic Shock; Vomiting	Triamcinolone Acetonide			S				Sanofi
	Actemra			S	Intravenous (not otherwise specified)	280 Mg		Not Reported
	Enbrel			S	Subcutaneous	25 Mg		Not Reported
	Anakinra			S		50 Mg, Qd		Not Reported
	Humira Ac			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	5 Mg, Qd		Sanofi
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg, Qw		Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Mg		Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	15707284	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2584423-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Sulfasalazine	C	Not Reported
	Wellbutrin	C	Not Reported
	Xeljanz	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	15712957	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2588343-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	16836959	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-27185		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Ciclosporin			S	Oral	Unknown		Not Reported
	Ciclosporin			S	Oral	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Gold	S	Unknown	Unknown	Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous	Unknown	Not Reported
Humira	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Imuran	S	Unknown	Unknown	Not Reported
Lyrica	S	Unknown	Unknown	Not Reported
Methotrexate	S	Unknown	Unknown	Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous	Unknown	Not Reported
Methotrexate	S	Oral	Unknown	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)		Not Reported
Mycophenolate Mofetil	S	Unknown	Unknown	Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Plaquenil	S	Unknown	Unknown	Not Reported
Plaquenil	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Unknown	Not Reported

Sulfasalazine	S	Unknown			Not Reported
Apo-Leflunomide	S	Unknown			Not Reported
Rituximab	S	Unknown	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Sodium Aurothiomalate	S	Unknown	Unknown		Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous	Unknown		Not Reported
Piroxicam	C	Unknown	Unknown		Not Reported
Prednisone	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	16977712	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201910001380			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Neutropenia; Pain In Extremity; Rash; White Blood Cell Count Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported
	Methotrexate			S	Unknown	Unk, Weekly		Not Reported
	Arava			S	Unknown	10 Mg, Qd		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Xeljanz			C		Unk		Not Reported
	Flurbiprofen			C		Unk		Not Reported
	Tylenol			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Prevacid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17404137	EXPEDITED (15-DAY)		CA, HO, OT	NVSC2020CA032705		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy;	Cosentyx			S	Unknown	Unk		Novartis

Arthropathy; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Off Label Use; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unknown	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Naprosyn	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17574330	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201711-006281			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Hydroxychloroquine			S	Unknown	300 Mg		Concordia
	Arava			S	Oral	10 Mg		Not Reported
	Gold			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Every Other Week		Not Reported
	Orencia			S	Subcutaneous	250 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

	Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Leflunomide	S	Unknown	10 Mg, Qd	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Sodium Aurothiomalate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	20 Mg, Weekly; Solution	Not Reported
	Methotrexate	S	Unknown	12.5 Mg	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Weekly	Not Reported
	Salazopyrin	S	Unknown		Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	25 Mg	Not Reported
	Enbrel	S	Unknown	50 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Every Six Weeks	Not Reported
	Orencia	S	Subcutaneous	25 Mg	Not Reported
	Bifidobacterium Bifidum	C			Not Reported
	Prednisone	C			Not Reported
	Sulfasalazine	C			Not Reported
	Celebrex	C			Not Reported
	Loperamide	C			Not Reported
	Pantoprazole	C			Not Reported
	Xeljanz	C			Not Reported
	Simponi	C			Not Reported
	Wellbutrin	C			Not Reported
	Plaquenil	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17574349	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201709-005363			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Concordia

Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Joint Swelling; Joint Swelling; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Toxicity To Various Agents; Visual Impairment; Visual Impairment	(Authorized Generic),Plaquenil Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Qd	Concordia
	(Authorized Generic),Plaquenil Leflunomide	S	Oral	20 Mg, Qd	Not Reported
	Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	125 Mg, Weekly	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Weekly	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
	Arava	S	Oral	20 Mg, Qd	Not Reported
	Arava	S	Unknown	20 Mg, Qd	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Cimzia	S	Unknown	Unk, Solution Subcutaneous	Not Reported
	Methotrexate	C		Unk	Not Reported
	Sulfasalazine	C		Unk	Not Reported
	Xeljanz	C		Unk	Not Reported
	Acetaminophen	C		Unk	Not Reported
	Depo-Medrol	C		Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Tylenol	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17574376	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201805-001688			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia
	Kevzara			S	Subcutaneous	20 Mg, Qow		Not Reported
	Leflunomide			S	Oral	20 Mg		Not Reported
	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Weekly		Not Reported
	Cyclosporin			S	Intracardiac	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Xeljanz			C		Unk		Not Reported
	Nexium			C		Unk		Not Reported
	Metformin			C		Unk		Not Reported
	Vitamin D			C		Unk		Not Reported
	Magnesium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17574713	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023101		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Hand	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	160 Milligram, Qwk		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Meloxicam	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17574715	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-013887			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Epistaxis; Headache; Insomnia; Nausea; Osteonecrosis Of Jaw; Transaminases Increased	Risedronate			S	Oral	35 Milligram, Every Week		Aurobindo
	Plaquenil			S	Unknown	300 Milligram, Once A Day		Not Reported
	Arava			S	Oral	20 Milligram, Once A Day		Not Reported
	Mycophenolate Mofetil			S	Oral	500 Milligram, Two Times A Day		Not Reported
	Mycophenolate Mofetil			S	Oral	1 Gram, Two Times A Day		Not Reported
	Azathioprine			C	Oral	50 Milligram, Once A Day		Not Reported
	Azathioprine			C	Oral	150 Milligram, Once A Day		Not Reported
	Azathioprine			C	Oral	100 Milligram, Two Times A Day		Not Reported
	Humira			C	Subcutaneous	40 Milligram (1 Every 2 Weeks)		Not Reported
	Ketoprofen			C	Unknown	Unk		Not Reported

Methotrexate	C	Oral	Unk		Not Reported
Methotrexate	C	Subcutaneous	25 Milligram, Every Week		Not Reported
Prolia	C	Subcutaneous	60 Milligram (1 Every 6 Months)		Not Reported
Rituximab	C	Intravenous (not otherwise specified)	1 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17574931	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003001751			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Hydroxychloroquine			S	Unknown	300-400 Unk		Concordia
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17575142	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-000867			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Hyperhidrosis	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Ipca
	Prednisolone			C	Unknown	Unk, Take As Directed		Not Reported
	Dermol			C	Unknown	Unk, Use As Directed		Not Reported
	Dermovate			C	Unknown	Unk, Apply 1-2 Times/Day Thinly To All Affected Areas		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17575254	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023112		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain;	Orencia			S	Unknown			Bristol Myers Squibb

Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Actemra	S	Unknown		Not Reported
	Apo-Prednisone	S	Oral	5 Milligram, Qd	Not Reported
	Arava	S	Unknown	20 Milligram, Qd	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Humira	S	Subcutaneous	20 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, 2 Every 1 Day	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, 2 Every 1 Day	Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram, 4 Every 1 Week	Not Reported
	Prednisone	S	Oral	5 Milligram, Qd	Not Reported
	Sulfasalazine	S	Unknown	1000 Milligram, 2 Every 1 Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17575456	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023128			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Intentional Product Use Issue; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft Tissue Swelling; Synovitis	Orencia			S	Intracavernous			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk, 2 Every 1 Day		Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported

	Darifenacin	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Diphenhydramine	C	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported
	Kadian	C	Unknown	Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Intra-articular	Not Reported
	Oxyneo	C	Unknown	Not Reported
	Pantoprazole Sodium Anhydrous	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Trimethoprim	C	Unknown	Not Reported
	Urispas	C	Unknown	Not Reported
	Vagifem	C	Vaginal	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17575525	NON-EXPEDITED			US-PFIZER INC-2020123929		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Therapeutic Product Effect Incomplete	Sulfasalazine			S	Oral	500 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S	Oral	200 Mg, 2x/Day		Not Reported
	Xeljanz Xr			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17575752	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023400		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Arthritis; Toxicity To Various Agents; Visual Impairment	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Qd	Not Reported
	Xeljanz	C	Oral	5 Gram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17575760	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020120639			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Psoriatic Arthropathy; Swelling; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Cosentyx			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17575864	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567757		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

	Prednisone	C	Oral	Not Reported
	Lyrica	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17576314	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023435		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Dyspnoea; Gait Disturbance; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral	200 Milligram, Bid		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tramadol			C	Unknown	100 Milligram		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17576658	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023436			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	4 Milligram/Kilogram		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported

Haemorrhage; Gait Disturbance; Gingival Bleeding; Headache; Infection; Intentional Product Use Issue; Joint Swelling; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Enbrel	S	Unknown	50 Milligram, Qd	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, 2 Every 1 Day	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Simponi	S	Unknown		Not Reported
	Prednisone	C	Unknown	50 Milligram, 1 Every 1 Day	Not Reported
	Prevacid	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	50 Milligram, 2 Every Q Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17577389	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023448		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rotator Cuff Syndrome; Swelling; Therapeutic Response Decreased; Tongue Ulceration; Tooth Infection	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Nystatin			S	Unknown			Not Reported
	Nystatin			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Tramadol	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Indometacin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17577584	EXPEDITED (15-DAY)		DS	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023530			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	162 Milligram		Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17577628	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023475		55 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Toxicity To Various Agents; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine	S	Unknown	400 Milligram		Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd		Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Qwk		Not Reported
Sulfasalazine	S	Oral	1 Gram, Qd		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17577694	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023552		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Celebrex			C	Unknown	200 Milligram, Bid		Not Reported
	Septra			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17577757	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023607		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported

Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Enbrel	S	Unknown	25 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Anakinra	C	Unknown	100 Milligram	Not Reported
	Ativan	C	Unknown	Unk	Not Reported
	Codeine	C	Unknown	Unk	Not Reported
	Darifenacin	C	Unknown		Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported
	Dilaudid	C	Unknown		Not Reported
	Diphenhydramine	C	Unknown	Unk	Not Reported
	Furosemide	C	Unknown	Unk	Not Reported
	Hydromorphone	C	Unknown	Unk	Not Reported
	Kadian	C	Unknown	Unk	Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Intra-articular	Unk	Not Reported
	Loperamide	C	Unknown	Unk	Not Reported
	Norflex [Orphenadrine Citrate]	C	Unknown		Not Reported
	Omnaris	C	Unknown	Unk	Not Reported
	Oxyneo	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Restasis	C	Unknown		Not Reported
	Rituximab	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported

Trimethoprim	C	Unknown			Not Reported
Urispas	C	Unknown	200 Milligram		Not Reported
Vagifem	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17577988	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023859			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578006	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023868			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Finger Deformity; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Methotrexate		S	Unknown		Not Reported
Remicade		S	Intravenous (not otherwise specified)		Not Reported
Rituximab		S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine		S	Unknown		Not Reported
Naproxen		C	Unknown	500 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578076	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023929			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Prednisone			C	Unknown	30 Milligram, Qd		Not Reported
	Methotrexate			C	Oral	15 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578415	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024447			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578458	EXPEDITED (15-DAY)		OT	US-JNJFOC-20200329683			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Gastric Disorder; Gastritis; Nail Discolouration; Nail Disorder; Nausea; Pancreatitis; Skin Lesion; Tuberculosis; Vomiting; Weight Decreased	Simponi Aria			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Spironolactone			C				Not Reported
	Verapamil			C				Not Reported
	Omeprazole			C				Not Reported
	Vitamin D /00107901/			C				Not Reported
	Calcium /00060701/			C				Not Reported
	Albuterol /00139501/			C				Not Reported
	Carafate			C				Not Reported
	Dulera			C				Not Reported
	Prednisone			C		5 Mg For The First 3 Days/ / -/ / Tablets Taper Dose Down		Not Reported
	Ipratropium Bromide			C				Not Reported

Albuterol Sulfate	C		Not Reported
Singulair	C		Not Reported
Claritin /00917501/	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578514	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020123955			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Enbrel			S	Unknown			Pfizer
	Methotrexate Sodium			S	Unknown			Pfizer
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578942	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024664		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	400 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578947	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024594		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Tofacitinib			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578991	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024991			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578997	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023964		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; General Symptom; Neck Pain; Off Label Use; Spinal Column Injury; Surgical Failure; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown	15 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17579024	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024270			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, Qwk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported

Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulphate	S	Unknown	200 Milligram, Bid	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral	2000 Milligram	Not Reported
Synthroid	C	Unknown		Not Reported
Methotrexate	C	Unknown	Unk, Qwk	Not Reported
Meloxicam	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	12701613	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1490		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral	2 In 1 Day		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Aleve	S	Unknown		Not Reported
Adalimumab	S	Subcutaneous		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Naproxen	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Cosentyx	S	Unknown		Not Reported
Naproxen Sodium	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Prednisone Acetate	S	Unknown		Not Reported
Naproxen	S	Unknown		Not Reported
Leflunomide	S	Unknown	Cyclical	Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Plaquenil	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported

Folic Acid	C	Unknown	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Not Reported
Hcq	C	Unknown	Not Reported
Acetaminophen And Codeine	C	Unknown	Not Reported
Celebrex	C	Unknown	Not Reported
Insulin	C	Unknown	Not Reported
Metformin	C	Unknown	Not Reported
Tylenol	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	12911486	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-048399			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Off Label Use; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Mirtazapine			S	Unknown	15 Milligram		Not Reported
	Hydroxychloroquine Phosphate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil S			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	13152994	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-004666		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Off Label Use; Osteoporosis; Pain; Rash; Surgery; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	14145032	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-095890			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Reaction; Drug Ineffective; Hospitalisation; Meningitis; Off Label Use	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Actemra			S	Unknown	1 Dosage Form		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	14917725	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-071465			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	577 Milligram		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	577 Absent		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	577 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	577 Absent		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	577 Milligram		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	577 Milligram		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported

[Hydroxychloroquine Sulfate]					
Simponi	S	Subcutaneous	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Simponi	S	Unknown	577 Milligram		Not Reported
Actemra	S	Unknown	Unk		Not Reported
Actemra	S	Unknown	Unk		Not Reported
Actemra	S	Unknown	577 Milligram		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk		Not Reported
Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
Methotrexate Sodium	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Oral	577.0 Milligram		Not Reported
Hydroxychloroquine	S	Unknown	577 Absent		Not Reported
Desoximetasone	C	Oral	Unk		Not Reported
Cortisone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	14921371	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043739		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	40 Milligram		Not Reported
	Leflunomide			S	Unknown			Not Reported

Naproxen Sodium	S	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported
Xeljanz	S	Oral	5 Mg, Bid		Not Reported
Naproxen	S	Unknown			Not Reported
Folic Acid	C	Unknown			Not Reported
Methotrexate	C	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	15674968	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573976-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Kineret			S	Subcutaneous	100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

	Methotrexate	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	15949326	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-010949			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, 2 Every 1 Day		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	16073575	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05670		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Infliximab			S	Unknown	Unknown		Not Reported

Swelling; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Actemra	S	Unknown	Unknown	Not Reported
	Anakinra	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Simponi	S	Subcutaneous	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Tocilizumab	S	Unknown	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Unknown	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Unknown	Not Reported
	Desoximetasone	C	Unknown	Unknown	Not Reported
	Methotrexate	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	16125465	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091994			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported

Humira	S	Subcutaneous	40 Milligram, Cyclical		Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous			Not Reported
Methotrexate	S	Oral	Unk Unk, Q2wk		Not Reported
Methotrexate Sodium	S	Oral	40 Mg (Titer), Q2wk		Not Reported
Methotrexate Sodium	S	Subcutaneous	Unk		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	16248273	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2761854-00		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Prednisolone			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	16439513	EXPEDITED (15-DAY)		DS, OT	CA-SAMSUNG BIOEPIS-SB-2019-14998		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased;	Etanercept			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not			Not Reported

Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Injection Site Reaction; Intentional Product Use Issue; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Decreased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Infliximab	S	otherwise specified)		Not Reported
	Adalimumab	S	Intravenous (not otherwise specified)		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Humira	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Enbrel	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Leflunomide	S	Oral	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Orencia	S			Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Rituximab	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Tocilizumab	S	Unknown	Unknown	Not Reported
	Tocilizumab	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Actemra	S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	16485230	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2835174-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Head Injury; Road Traffic Accident	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	16740243	EXPEDITED (15-DAY)		HO, OT	PHHY2019CA196426		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Joint Swelling; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Product Use In Unapproved Indication; Red Blood Cell Sedimentation Rate	Aclasta			S	Intravenous (not otherwise specified)	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk, Qw		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	1 Df, Qd		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Not Reported

Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Stenosis; Treatment Failure	Plaquenil	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2 G, Qd	Not Reported
	Tramacet	S	Unknown		Not Reported
	Actonel	C	Unknown	35 Mg, Qw	Not Reported
	Calcium	C	Unknown		Not Reported
	Lorazepam	C	Unknown	1 Mg, Qd	Not Reported
	Lyrica	C	Oral	150 Mg, Bid	Not Reported
	Metformin	C	Unknown	5 Mg, Qd	Not Reported
	Metformin	C	Unknown	500 Mg, Bid	Not Reported
	Methylprednisolone Acetate	C	Subcutaneous	Unk Unk, Qmo	Not Reported
	Methylprednisolone Acetate	C	Intramuscular	40 Mg, Qmo	Not Reported
	Methylprednisolone Acetate	C	Subcutaneous	Unk	Not Reported
	Methylprednisolone Acetate	C	Intramuscular	40 Mg, Qmo	Not Reported
	Methylprednisolone Acetate	C	Unknown	Unk	Not Reported
	Nortriptyline	C	Unknown	Unk	Not Reported
	Nortriptyline	C			Not Reported
	Premarin	C	Unknown	0.625 Mg, Unk	Not Reported
	Tylenol	C	Unknown		Not Reported
	Vagifem	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Nortriptyline Hydrochloride	C	Unknown	20 Mg, Qd	Not Reported
	Nortriptyline Hydrochloride	C	Unknown	Unk	Not Reported
	Risedronate Sodium	C	Unknown	35 Mg, Every Week	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	16740961	EXPEDITED (15-DAY)		HO, OT	DE-ROCHE-2386588			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; Arthralgia; Arthropathy; Atrial	Roactemra			S	Subcutaneous			Not Reported
	Roactemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported

Fibrillation; Bronchitis; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Ambrisentan		S	Unknown	30 Mg, Qd	Not Reported
	Ambrisentan		S	Unknown	30 Milligram, Qd	Not Reported
	Lyrica		S	Unknown	100 Mg, Tid (1 - 1 - 1)	Not Reported
	Sildenafil Citrate		S	Unknown	60 Milligram, Daily Dose	Not Reported
	Volibris		S	Oral	30 Milligram, Qd	Not Reported
	Volibris		S	Oral	1 Dosage Form, Qd	Not Reported
	Quensyl		S	Unknown	1 Df, Bid (1 - 0 - 1)	Not Reported
	Spasmolyt		S	Unknown	30 Mg (0 -0 -1)	Not Reported
	Spasmolyt		S	Unknown	15 (Unit Not Specified), Qd ((1 - 0 - 0)	Not Reported
	Omeprazole		S	Oral	1 Df, Bid (1 - 0 - 1)	Not Reported
	Ramipril		S	Oral	1 Df, Bid (1 - 0 - 1)	Not Reported
	Eliquis		S	Unknown	2.5 Mg Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17390605	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-006953		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	400 Milligram		Not Reported
	Xeljanz			S	Oral	5 Milligram(2 Every One Week)		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

Naproxen Sodium	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Folic Acid	C	Unknown			Not Reported
Methotrexate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17578578	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023106		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Back Disorder; Drug Ineffective; Drug Intolerance; Mouth Ulceration; Vasculitic Rash	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Q4wk		Bristol Myers Squibb
	Orencia			S	Unknown	500 Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Q2wk		Not Reported
	Leflunomide			S	Oral	20 Unk		Not Reported
	Methotrexate			S	Unknown	Unk, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram, Qd		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17578721	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003001831			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cushingoid; Diarrhoea; Nausea; Nightmare; Renal Pain; Sleep Terror; Therapeutic Response Decreased; Treatment Failure; Weight Increased	Hydroxychloroquine	S	Unknown	Unk	Concordia
	Arava	S	Oral	20 Mg, Qd	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	5 Mg, Qd	Not Reported
	Sulfasalazine	S	Oral	1 G, Bid	Not Reported
	Methotrexate	S	Oral	25 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Weekly	Not Reported
	Azathioprine	C			Not Reported
	Humira	C		Unk	Not Reported
	Leucovorin	C		Unk	Not Reported
	Prevnar 13	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17578725	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201703-001913			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Arthropathy; Condition Aggravated; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Finger Deformity; Limb Operation; Off Label Use; Pain; Peripheral Swelling; Peripheral Swelling; Rash; Swelling; Tendon Disorder; Tendon Operation; Tenosynovitis; Treatment Failure; Urticaria; Urticaria; Wrist Surgery	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unknown, Tablet		Concordia
	Hydroxychloroquine			S	Unknown	Unknown		Concordia
	Apo-Hydroxyquine			S	Unknown	Unknown		Not Reported
	Apo-Hydroxyquine			S	Oral	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	Unknown		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rocuronium Bromide	S	Unknown	Unknown	Not Reported
	Rocuronium Bromide	S	Unknown	Unk	Not Reported
	Codeine	S	Unknown	Unknown	Not Reported
	Gold	S	Unknown	Unknown	Not Reported
	Sulfamethoxazole/Trimethoprim	S	Unknown	Unknown	Not Reported
	Benzylpenicillin Sodium	S	Unknown	Unknown	Not Reported
	Phenoxymethylpenicillin Potassium	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Prednisone	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17578782	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023426		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Inflammation; Joint Stiffness; Joint Swelling; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	640 Milligram, Q4wk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17578902	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568831		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastric Ulcer; Malaise; Throat Cancer	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17578910	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023485			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown	162 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

	Azathioprine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17579095	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003001832			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Diarrhoea; Diarrhoea; Nausea; Renal Failure	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Concordia
	Leflunom|De			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17579314	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US-000918			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree; Cardiac Failure; Cardiomyopathy; Cardiotoxicity; Renal Impairment	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Ipca
	Furosemide			S	Intravenous (not otherwise specified)	Unk		Ipca
	Prednisone			C	Unknown	Unk		Not Reported
	Mycophenolate			C	Unknown	Unk		Not Reported
	Rituximab			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17579324	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1483			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Other			Not Reported

	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Celebrex	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17579472	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567801		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Synovitis	Rituxan			S	Intravenous drip			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Parenteral			Not Reported

	Orencia	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17579865	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1208924		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Levofloxacine			S	Oral	1000 Mg		Teva
	Plaquenil 200 Mg, Comprime Pellicule			S	Oral	2 Dosage Forms		Not Reported
	Ideos			S	Oral	2 Dosage Forms		Not Reported
	Acarizax			S	Oral			Not Reported
	Lutenyl			C				Not Reported
	Cortancyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17579885	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025463		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17580009	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020124022			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis	Methotrexate Sodium			S		20 Mg, Weekly (Therapy Duration: 7 Years)		Pfizer
	Enbrel			S		Unk (Therapy Duration: 9 Months)		Pfizer
	Rituximab			S		Unk (Therapy Duration: 3 Years)		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk (1 Every 2 Weeks, Therapy Duration: 346 Days)		Not Reported
	Hydroxychloroquine			S		200 Mg, 2x/Day (Therapy Duration: 9 Years)		Not Reported
	Remicade			S		Unk (Therapy Duration: 2 Years)		Not Reported
	Xeljanz			C		5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17580309	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023667		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported

Prednisone	S	Unknown			Not Reported
Prednisone Acetate	S	Unknown			Not Reported
Xeljanz	S	Oral	5 Milligram, Bid		Not Reported
Folic Acid	C	Unknown			Not Reported
Hydroxychloroquine Sulfate	C	Unknown			Not Reported
Naproxen	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581498	NON-EXPEDITED			US-PFIZER INC-2020122192		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer
	Actemra			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581796	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025438			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown	12.5 Milligram, Bid	Not Reported
	Arava	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581877	DIRECT		OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Abnormal Weight Gain; Alopecia; Chest Pain; Dizziness; Dyspnoea; Fatigue; Joint Swelling; Nausea; Photosensitivity Reaction; Syncope; Tremor	Hydroxychloroquine 200 Mg			S	Oral	Quantity:2 Tablet(S);	5 YR	Not Reported
	Prem-Pro 0.3mg/1.5mg			C				Not Reported
	Ventolin Inhaler			C				Not Reported
	Vit B (Complex)			C				Not Reported
	Vitamin C			C				Not Reported
	Vitamin D			C				Not Reported
	Zinc			C				Not Reported
	Calcium			C				Not Reported
	Magnesium			C				Not Reported
	Cod Liver Oil			C				Not Reported
	Grape Seed Extract			C				Not Reported
	St Johns Wort			C				Not Reported
	Stainging Nettle			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581909	EXPEDITED (15-DAY)		DE, HO, LT, OT	NVSC2020CA083709			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S	Unknown	Unk		Novartis
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

Methotrexate	S	Unknown	Unk		Not Reported
Methotrexate	S				Not Reported
Actemra	S	Unknown	Unk		Not Reported
Actemra	S				Not Reported
Anakinra	S	Unknown	Unk		Not Reported
Anakinra	S				Not Reported
Apo-Leflunomide	S	Unknown	Unk		Not Reported
Apo-Leflunomide	S				Not Reported
Enbrel	S	Unknown	Unk		Not Reported
Enbrel	S				Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Humira	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S				Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S				Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S				Not Reported
Sulfasalazine	S	Unknown	500 Mg		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581930	EXPEDITED (15-DAY)		HO, LT	ES-MYLANLABS-2020M1030615		44 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Drug Interaction	Methotrexate			S	Subcutaneous	10 Milligram, Qw		Not Reported
	Dolquine			S	Oral	200 Milligram, Bid (12 Hours)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581934	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020CA083373			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Intravenous (not otherwise specified)	Unk		Novartis
	Ilaris			S	Subcutaneous	Unk		Novartis
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S				Not Reported
	Methotrexate Sodium			S	Intra-arterial	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Oxyquinoline Sulfate			S	Unknown	Unk		Not Reported
	Oxyquinoline Sulfate			S				Not Reported
	Remicade			S	Unknown	Unk		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	500 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581956	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020CA083719		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Ilaris			S	Unknown	Unk		Novartis
	Ilaris			S	Intravenous (not otherwise specified)	Unk		Novartis
	Ilaris			S	Subcutaneous	Unk		Novartis
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S				Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Humira	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Oral	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Orencia	S				Not Reported
Orencia	S	Unknown	Unk		Not Reported
Orencia	S				Not Reported
Remicade	S	Unknown	Unk		Not Reported
Remicade	S				Not Reported
Remicade	S	Unknown	Unk		Not Reported
Remicade	S				Not Reported
Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
Sodium Aurothiomalate	S				Not Reported
Sulfasalazine	S	Unknown	500 Mg		Not Reported
Sulfasalazine	S				Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Sulfasalazine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581969	EXPEDITED (15-DAY)		HO, LT	ES-MYLANLABS-2020M1030618		30 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Mycophenolate Mofetil			S	Oral	500 Milligram, Bid		Not Reported
	Dolquine			S	Oral	200 Milligram, Bid		Mylan
	Rituximab			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17583060	EXPEDITED (15-DAY)		DS	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025465		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fine Motor Skill	Orencia			S	Intravenous (not			Bristol Myers Squibb

Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete				otherwise specified)	
	Anakinra		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous drip	Not Reported
	Humira		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17583075	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025482			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Bronchitis; Diarrhoea; Drug Ineffective; Dyspepsia; Fear; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Treatment Failure	Orencia			S	Endocervical			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Methotrexate			C	Subcutaneous	25 Milligram, Qd		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17583096	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025534			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Orencia		S	Intravenous (not otherwise specified)		Bristol Myers Squibb
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17583157	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025394			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Myochrysine			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	12889782	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP013285		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex

Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Limb Deformity; Loose Body In Joint; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Apo-Leflunomide	S	Oral	5 Mg, Q.12h		Apotex
	Apo-Leflunomide	S	Unknown	Unk Unk, Bid		Apotex
	Apo-Naproxen	S	Unknown	Unk		Apotex
	Actemra	S	Unknown	Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Xeljanz	S	Oral	5 Mg, Q.12h		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Adalimumab	S	Subcutaneous			Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Actemra	C	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported
	Humira	C	Subcutaneous	Unk		Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil /00072602/	C	Unknown			Not Reported
	Folic Acid	C	Unknown			Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	12914312	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091576		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Off Label Use; Red Blood Cell	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Sodium Aurothiomalate			S	Unknown	Unk, Qwk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk, Qd		Not Reported

Sedimentation Rate Increased; Urticaria	Gold	S	Unknown	Unk, Qwk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Oral	22.5 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Parenteral	25 Milligram, Qwk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	22.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Parenteral	25 Milligram, Qwk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Phosphate	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Subcutaneous	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Tocilizumab	C	Unknown	Unk	Not Reported
	Azathioprine	C	Unknown	Unk, Qd	Not Reported
	Ciclosporin	C	Unknown	Unk	Not Reported
	Minocycline	C	Unknown	Unk	Not Reported
	Penicillamine	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	6 Milligram, Bid	Not Reported

Actemra	C	Unknown	Unk		Not Reported
Cyclosporine	C	Unknown	Unk		Not Reported
Prednisolone	C	Unknown	6 Milligram, Qd		Not Reported
D-Penicillamine	C	Unknown	Unk		Not Reported
Phenylbutazone	C	Unknown			Not Reported
Methotrexate	C	Parenteral	25 Milligram, Q4wk		Not Reported
Humira	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	13057420	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-1869749		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	13057569	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015705		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Neutropenia; Platelet Count Decreased; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Qd		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Advil /00109201/			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Ketorolac			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	20 Mg, Q.Wk.		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	13059083	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015740		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Joint Swelling; Pain; Shoulder Operation; Therapeutic Response Decreased	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

	Orencia	S	Unknown	Unk		Not Reported
	Plaquenil /00072602/	S	Unknown	Unk		Not Reported
	Sulfasalazine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	13180365	EXPEDITED (15-DAY)		HO, OT	PHHY2017CA012856		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Methotrexate			S	Unknown	Unk		Not Reported
	Neoral			S	Unknown	Unk Unk, Unknown		Novartis
	Celebrex			S	Unknown	Unk Unk, Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unk Unk, Unknown		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unknown		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unknown		Not Reported
	Imuran			S	Unknown	Unk Unk, Unknown		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk, Unknown		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	13968018	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017267		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Gastrooesophageal Reflux Disease; Hepatic Enzyme	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Apotex
	Apo-Hydroxyquine			S	Unknown	200 Mg, Bid		Apotex
	Apo-Leflunomide			S	Unknown			Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex

Increased; Hypokinesia; Joint Range Of Motion Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Stiffness; Nausea; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Delayed	Leflunomide	S	Unknown	Unk	Apotex
	Methotrexate	S	Unknown	25 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	20 Mg, Qd	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Unknown	25 Mg, Q.Wk.	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Mg, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Unknown	200 Mg, Unk	Not Reported
	Cortisone	C	Unknown		Not Reported
	Prednisone	C	Unknown	5 Mg, Qd	Not Reported
	Tylenol Arthritis	C	Unknown		Not Reported
	Naprosyn /00256201/	C	Unknown		Not Reported
	Rabeprazole	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	14692979	EXPEDITED (15-DAY)		DE, HO, LT, OT	PHHY2018CA055436		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Death; Deep Vein Thrombosis; Diverticulitis; Drug	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S	Intravenous (not otherwise specified)	Unk		Novartis
	Ilaris			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported

Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S			Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S			Not Reported
	Sulfasalazin	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazin	S			Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S			Not Reported

Marijuana	S	Unknown			Not Reported
Minocycline Hydrochloride	S	Unknown			Not Reported
Minocycline	S	Unknown			Not Reported
Oxyquinoline Sulfate	S	Unknown			Not Reported
Oxyquinoline Sulfate	S				Not Reported
Cannabis Sativa	S	Unknown			Not Reported
Oxycodone	S	Unknown	10 Mg, Unk		Not Reported
Xeljanz	C	Oral	2 Df, Qd		Not Reported
Xeljanz	C	Unknown	5 Mg		Not Reported
Rituximab	C	Unknown			Not Reported
Kineret	C	Unknown	Unk		Not Reported
Lyrica	C	Unknown			Not Reported
Prednisone	C	Unknown	1 Df, Qd		Not Reported
Urelumab	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	15042955	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021658		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Hip Arthroplasty; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Etanercept			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg, Q.Wk.		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

Remicade	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Actemra	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Leflunomide	C	Unknown	Unk		Not Reported
Remicade	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	15411090	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186044		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	15635401	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105895			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported

Therapeutic Response Decreased	Hydroxychloroquine		S	Unknown	200.0 Mg, Qd	Not Reported
	Methotrexate		S	Oral	25.0 Mg, Qwk	Not Reported
	Myochrysine		S	Intramuscular	25 Mg, Qwk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Arava		S	Unknown	Unk	Not Reported
	Gold Sodium Thiomalate		S	Unknown		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	15680306	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2575130-00		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger Deformity; Limb Operation; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rocuronium			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

Rocuronium Bromide	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	15867265	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190123564		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-Reactive Protein Increased; Diverticulitis; Drug Ineffective; Drug Intolerance; Infection; Synovitis	Simponi Iv			S	Intravenous (not otherwise specified)			Not Reported
	Simponi Iv			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	15946323	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-010990		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb

Drug Intolerance; Glaucoma; Herpes Zoster; Nasopharyngitis; Off Label Use; Therapeutic Product Effect Decreased	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	1 Dosage Form, Qwk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Arava	C	Unknown		Not Reported
	Codein	C	Unknown		Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Tylenol	C	Unknown		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Prednisone	C	Oral		Not Reported
	Acetaminophen	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	16125329	EXPEDITED (15-DAY)		OT	PHHY2019CA064258		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Ciclosporin			S	Subcutaneous			Novartis
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported

Methotrexate	S	Oral	20 Mg, Unk	Not Reported
Methotrexate	S	Subcutaneous	20 Mg, Unk	Not Reported
Methotrexate	S	Oral	20 Mg, Unk	Not Reported
Methotrexate	S	Subcutaneous	20 Mg, Unk	Not Reported
Methotrexate	S	Oral	20 Mg,Unk	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Apo-Leflunomide	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Every 1 Week	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Every 1 Week	Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg, Unk	Not Reported
Rituxan	S	Intravenous drip	Unk	Not Reported
Rituxan	S	Intravenous drip	Unk	Not Reported
Sulfasalazine	S	Oral	Unk	Not Reported
Xeljanz	C	Unknown	Unk, Qd	Not Reported
Xeljanz	C	Oral	10 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	16128012	EXPEDITED (15-DAY)		OT	PHHY2019CA064350		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Neoral	S	Subcutaneous	Unk	Novartis
	Neoral	S	Oral	Unk	Novartis
	Ciclosporin	S	Subcutaneous	Unk	Novartis
	Methotrexate	S	Subcutaneous	20 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Methotrexate	S	Oral	20 Mg, Unk	Not Reported
	Methotrexate	S	Oral	20 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	16480411	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Oral	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Desoximetasone			C	Unknown	Unknown		Not Reported
	Methotrexate			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	16536778	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1071381			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Contraindicated Product	Ciprofloxacin			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Clindamycin			S	Unknown			Actavis

Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Codeine	S	Unknown	Not Reported
	Enalapril	S	Unknown	Teva
	Hctz	S	Unknown	Ivax
	Losartan	S	Unknown	Teva
	Methotrexate	S	Unknown	Barr
	Methotrexate	S	Subcutaneous	Barr
	Methotrexate	S	Subcutaneous	Barr
	Metoprolol Tartrate	S	Unknown	Not Reported
	Moxifloxacin Hydrochloride	S	Unknown	Teva
	Moxifloxacin Hydrochloride	S	Unknown	Teva
	Pantoprazole Magnesium	S	Unknown	Teva
	Penicillin G	S	Unknown	Teva
	Cefalexin	S	Unknown	Not Reported
	Enalapril Maleate	S	Unknown	Teva
	Losartan	S	Unknown	Teva
	Arava	S	Unknown	Not Reported
	Biaxin	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Fosamax	S	Unknown	Not Reported
	Hydralazine Hydrochloride	S	Unknown	Not Reported
	Keflex	S	Unknown	Not Reported
	Levaquin	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Pariet	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Diazide (Gliclazide)	S	Unknown	Not Reported
	Lopressor	S	Unknown	Not Reported

Tecta	S	Unknown		Not Reported
Xeljanz	S	Oral	100 Milligram Daily;	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Isoniazid	S	Unknown		Not Reported
Cipro	S	Unknown		Not Reported
Penicillin Nos	S	Unknown		Not Reported
Esomeprazole	C	Unknown		Not Reported
Gold	C			Not Reported
Hydroxychloroquine	C			Not Reported
Iron Sucrose	C	Unknown		Not Reported
Prednisone	C	Unknown	8.5 Milligram Daily;	Not Reported
Colchicine	C			Not Reported
Coversyl [Perindoprilerbumine]	C			Not Reported
Hydroxychloroquine Sulfate	C	Unknown		Not Reported
Leucovorin [Folinic Acid]	C			Not Reported
Levothyroxine Sodium	C			Not Reported
Ranitidine	C			Not Reported
Venofer	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	16767573	EXPEDITED (15-DAY)		OT	PHHY2018CA068442		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Oral	Unk		Novartis
	Ciclosporin			S	Unknown			Novartis
	Adalimumab			S	Subcutaneous	40 Mg, Biw		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Biw		Not Reported

Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
Apo Hydroxyquine	S	Subcutaneous	Unk	Not Reported
Apo Hydroxyquine	S	Oral	Unk	Not Reported
Apo Leflunomida	S	Unknown		Not Reported
Enbrel	S	Unknown	50 Mg, Biw	Not Reported
Enbrel	S	Unknown	50 Mg, Biw	Not Reported
Xeljanz	S	Oral	5 Mg, Bid	Not Reported
Methotrexate	S	Oral	20 Mg, Qw	Not Reported
Methotrexate	S	Subcutaneous	20 Mg, Qw	Not Reported
Methotrexate	S	Oral	20 Mg, Qw	Not Reported
Methotrexate	S	Subcutaneous	25 Mg, Qw	Not Reported
Methotrexate	S	Oral	20 Mg	Not Reported
Methotrexate	S	Oral	20 Mg	Not Reported
Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
Orencia	S	Unknown	75 Mg, Qw	Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Unknown	40 Mg, Biw	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Plaquenil	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Oral	500 Mg, Qd	Not Reported

	Risedronate	C	Oral	35 Mg, Qw		Not Reported
	Rituxan	C	Intravenous (not otherwise specified)			Not Reported
	Arava	C	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	16792405	EXPEDITED (15-DAY)		HO	JP-GLAXOSMITHKLINE-JP2019JPN160709		50 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Focal Segmental Glomerulosclerosis	Benlysta			S	Subcutaneous	200 Mg		Glaxosmithkline
	Benlysta			S	Subcutaneous	200 Mg		Glaxosmithkline
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Predonine			C		Unk		Not Reported
	Mycophenolate Mofetil Capsule			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	16982578	EXPEDITED (15-DAY)		DS, HO, OT	CA-CELGENEUS-CAN-20191009548		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug	Otezla			S	Unknown	60 Milligram		Celgene
	Otezla			S	Unknown			Celgene
	Alendronate Sodium			S	Unknown	70 Milligram		Not Reported
	Alendronate Sodium			S	Unknown	70 Milligram		Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	500 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported

Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Ibuprofen	S	Oral		Not Reported
	Apo-Ibuprofen	S	Oral	600 Milligram	Not Reported
	Apo-Ibuprofen	S	Oral	600 Milligram	Not Reported
	Infliximab	S	Oral		Not Reported
	Infliximab	S			Not Reported
	Methotrexate	S	Unknown	1.7143 Milligram	Not Reported
	Methotrexate	S	Unknown	1.7857 Milligram	Not Reported
	Methotrexate	S	Unknown	1.4286 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	2.5 Milligram	Not Reported
	Methotrexate	S	Unknown	1.4286 Milligram	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	7.1429 Milligram	Not Reported
	Methotrexate	S	Unknown	5.7143 Milligram	Not Reported
	Methotrexate	S	Unknown	6.8571 Milligram	Not Reported
	Methotrexate	S	Unknown	17.5 Milligram	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported

Orencia	S	Subcutaneous		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Unknown	1000 Milligram	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Simponi	S	Subcutaneous		Not Reported
Stelara	S	Subcutaneous		Not Reported
Sulfasalazine	S	Endocervical		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Ciclosporin	C	Unknown		Not Reported
Diphenhydramine Hydrochloride	C	Unknown		Not Reported
Colchicine	C	Oral		Not Reported
Dexilant	C	Unknown		Not Reported
Febuxostat	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Gravol	C	Unknown		Not Reported
Mogadon	C	Oral		Not Reported
Nitrazepam	C	Oral	5 Milligram	Not Reported
Oxycodone	C	Unknown		Not Reported
Prednisone	C	Unknown	20 Milligram	Not Reported
Uloric	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	16988122	EXPEDITED (15-DAY)		OT	CA-SA-2019SA298961			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal	Cefixime			S	Unknown	Unk		Not Reported
	Bisoprolol Salt Not Specified			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Morphine Salt Not Specified			S				Not Reported
	Nifedipine			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Sanofi
	Prednisone			S	Unknown			Not Reported
	Clonazepam			S	Unknown	Unk		Not Reported
	Zantac			S	Unknown			Sanofi
	Zopiclone			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Oral	100 Mg		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	5 Mg/Kg Q0, 2, 6, 8 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17455140	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202002000974			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Maternal Exposure During Pregnancy; Toxicity To Various Agents	Hydroxychloroquine			S		Unk		Concordia
	Hydroxychloroquine			S		400 Mg, Qd		Concordia
	Hydroxychloroquine			S		Unk		Concordia
	Azathioprine			S		50 Mg, Qd		Not Reported
	Azathioprine			S		Retreatment With Low-Dose 50 Mg		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Prednisone			S		Unk		Not Reported
	Prednisone			S		Moderate Doses Of		Not Reported

			Prednisone	
	Prednisone	S	2.5 Mg, Qd	Not Reported
	Belimumab	S	Unk	Not Reported
	Belimumab	S	10 Mg/Kg, Monthly	Not Reported
	Belimumab	S	Unk, Resumed 2 Weeks After Delivery	Not Reported
	Mycophenolate	C	Unk	Not Reported
	Mycophenolate	C	Switching Back	Not Reported
	Mycophenolate	C	Continued During The Initial 6 Months Of Belimumab Infusions And Then Tapered Off	Not Reported
	Warfarin	C	Unk	Not Reported
	Warfarin	C	Resumed Warfarin	Not Reported
	Low-Molecular-Weight Heparin	C	Unk	Not Reported
	Enoxaparin	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17533248	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200309558		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Off Label Use; Product Use In Unapproved Indication; Psoriatic Arthropathy; Rheumatoid Arthritis; Sleep Disorder; Uveitis	Stelara			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Otezla	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Myochrysine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Salazopyrin	S	Unknown	Not Reported
	Sirukumab	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Minocycline	S	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583205	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024031		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported

Erythematosus	Enbrel		S	Subcutaneous	Unk	Not Reported
	Folic Acid		S	Unknown	500 Milligram	Not Reported
	Fosamax		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram, Q12h	Not Reported
	Methotrexate		S	Oral	25 Milligram	Not Reported
	Phthalylsulfathiazole		S	Unknown	Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]		S	Unknown	Unk	Not Reported
	Rituximab		S	Intravenous drip	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583207	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025557		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583283	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-000888			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Drug Ineffective; Transient Ischaemic Attack; Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Warfarin Sodium			S	Unknown	Unk		Ipca
	Clopidogrel			S	Unknown	Unk		Not Reported
	Atorvastatin			S	Unknown	Unk		Not Reported
	Apixaban			S	Unknown	Unk		Not Reported

	Rivaroxaban	S	Unknown	Unk		Not Reported
	Low Molecular Weight Heparin	C	Unknown	Unk		Not Reported
	Isoniazid	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583491	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568766			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cortisone Acetate			C	Subcutaneous			Not Reported
	Desoximetasone			C	Subcutaneous			Not Reported
	Diclofenac			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583496	EXPEDITED (15-DAY)		OT	CA-ROCHE-2569483		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Cimzia	S	Subcutaneous	Single Use Prefilled Syringe	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Arava	C	Unknown		Not Reported
	Codeine	C	Unknown		Not Reported
	Lyrica	C	Oral		Not Reported
	Prednisone	C	Oral		Not Reported
	Tylenol	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583521	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023661		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Drug Ineffective; Hypersensitivity; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Alendronate Sodium			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported

Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	400 Milligram	Not Reported
	Cortisone Acetate	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	400 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	40 Milligram	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Q12h	Not Reported
	Sulfathalidine	S	Unknown	Unk	Not Reported
	Diclofenac	C	Unknown	50 Milligram	Not Reported

	Salazopyrin			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583562	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1479		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583564	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1490			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583582	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1504			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Psoriatic Arthropathy; Swelling; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583834	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003001844			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neutropenia; Rash	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	10 Mg, Qd		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Salazopyrin			C		Unk		Not Reported
	Solganal			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Codeine			C		Unk		Not Reported
	Flurbiprofen			C		Unk		Not Reported
	Cortisone			C	Intra-articular	Unk		Not Reported
	Tylenol			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Gold			C		Unk		Not Reported
	Prevacid			C		Unk		Not Reported
	Penicillamine			C		Unk		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583875	EXPEDITED (15-DAY)		OT	CA-ROCHE-2523564		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Diastolic Abnormal; Bone Marrow Toxicity; C-Reactive Protein Increased; Intentional Product Use Issue; Neuropathy	Rituxan			S	Intravenous (not otherwise specified)	1 Every Week For 4 Dose		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported

Peripheral; Off Label Use; Paraesthesia; Rash; Thrombocytopenia	Leflunomide	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Acetaminophen	C	Oral	Not Reported
	Diphenhydramine	C	Oral	Not Reported
	Lyrica	C		Not Reported
	Synthroid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583878	NON-EXPEDITED		DE	NVSC2020US084343		30 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malignant Melanoma Stage Iv; Malignant Neoplasm Progression	Dabrafenib			S	Unknown	150 Mg, Bid		Novartis
	Dabrafenib			S				Novartis
	Trametinib			S	Unknown	2 Mg, Qd		Not Reported
	Trametinib			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk, 400 To 600 Mg, Bid		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583912	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567774		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling;	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Methotrexate		S	Subcutaneous	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583952	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568809			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Rituximab			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584003	EXPEDITED (15-DAY)		HO	CA-ROCHE-2571253			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count	Rituxan			S	Unknown	Solution Intravenous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Decreased	Methotrexate	S	Unknown	Solution		Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Remicade	S	Unknown	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584031	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-241562		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis; Drug Resistance; Gastrointestinal Disorder; Pseudomonal Skin Infection; Therapeutic Product Effect Incomplete; Treatment Failure	Triamcinolone			S		Unk		Ranbaxy
	Tacrolimus			S	Topical	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sun
	Clobetasol			S	Topical	Unk		Taro
	Pentoxifylline			S	Unknown	Unk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584210	EXPEDITED (15-DAY)		OT	NVSC2020CA083918		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Remicade			S	Unknown	3 Mg (Powder For Solution)		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported

	Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Unk (Solution)	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584216	EXPEDITED (15-DAY)		OT	NVSC2020CA082940		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Cyclosporine			S	Unknown	Unk		Novartis
	Adalimumab			S	Subcutaneous	40 Mg, Unknown		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unknown		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qd		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unknown		Not Reported
	Methotrexate			S	Oral	20 Mg, Qd		Not Reported
	Xeljanz			S	Oral	Unk		Not Reported
	Xeljanz			S	Oral	2 Df, Qd		Not Reported
	Sulfasalazine			S	Oral	1 Df, Qd		Not Reported
	Remicade			S	Intravenous (not	3 Mg/Kg, Unknown		Not Reported

			otherwise specified)		
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	75 Mg, Qmo	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Unknown	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Oral	2000 Mg, Bid	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	40 Mg, Q2w	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unknown	Not Reported
	Arava	C	Oral	1 Df, Qd	Not Reported
	Cimzia	C	Subcutaneous	1 Df, Q2w	Not Reported
	Risedronate	C	Oral	1 Df, Qw	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584497	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020125866			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Hypersensitivity; Speech Disorder Developmental; Treatment Failure	Enbrel			S	Unknown			Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Codeine			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported

	Prednisone	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584625	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020127462		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Infection; Leukopenia; Neutropenia	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Azathioprine			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584658	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020127350			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Infection; Leukopenia; Neutropenia; Therapeutic Response Decreased	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584988	EXPEDITED (15-DAY)		OT	GB-TORRENT-00023236		29 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Drug Ineffective; Transient Ischaemic Attack;	Apixaban			S	Unknown	Unknown		Unknown
	Warfarin			S	Unknown	Unknown		Unknown
	Rivaroxaban			S	Unknown	Unknown		Unknown

Treatment Failure	Clopidogrel		S	Unknown	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Unknown	Unknown
	Atorvastatin		S	Unknown	Unknown	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585091	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568730			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculin Test Positive	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	Solution		Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Amoxicillin Trihydrate;Clavulanate Potassium			C	Unknown			Not Reported
	Amoxil [Amoxicillin]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585193	EXPEDITED (15-DAY)		OT	CA-ROCHE-2570007			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Eczema; Sepsis; Urinary Tract Infection	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Morphine	S	Unknown		Not Reported
	Cbd Oil	C			Not Reported
	Dronabinol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585240	EXPEDITED (15-DAY)		OT	NVSC2020CA083916		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Methotrexate			S	Subcutaneous	20 Mg, Unknown		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Neoral			S	Oral	Unk		Novartis
	Rituximab			S	Endocervical	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Novartis
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	Unk (Solution)		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unknown		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, Unknown		Not Reported
	Simponi			S	Subcutaneous	Unk (Solution)		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Xeljanz			C	Unknown	5 Mg, Qd 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585302	EXPEDITED (15-DAY)		OT	CA-SA-2020SA075362		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthropathy; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Knee Arthroplasty; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Musculoskeletal Disorder; Skin Warm; Spinal Stenosis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Hydroxychloroquine Sulfate			S	Oral			Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi
	Arava			S	Oral			Sanofi
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous	Unk, 1x		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiosulfate			C				Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Qw		Not Reported
	Prednisone			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585303	EXPEDITED (15-DAY)		OT	CA-SA-2020SA075074		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Drug Intolerance; Joint Swelling; Rheumatoid Factor Positive; X-Ray Abnormal	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Tofacitinib Citrate			S				Not Reported
	Actemra			S				Not Reported
	Diovan			C				Not Reported
	Docosahexanoic Acid;Eicosapentaenoic Acid			C				Not Reported

Sertraline	C		Not Reported
Valtrex	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585304	EXPEDITED (15-DAY)		OT	CA-SA-2020SA075084		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Arthralgia; Chronic Sinusitis; Diverticulum; Drug Ineffective; Haemochromatosis; Impaired Work Ability; Irritable Bowel Syndrome; Joint Swelling; Nausea; Osteoporosis; Treatment Failure	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Arava			S	Unknown			Sanofi
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585306	EXPEDITED (15-DAY)		OT	CA-SA-2020SA074997			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Gastrointestinal Disorder; Rash	Plaquenil			S		Unk G		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Methotrexate			C	Subcutaneous	25 Mg, Qw		Not Reported
	Sulfasalazine			C		2 G		Not Reported
	Venlafaxine Hydrochloride			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585763	EXPEDITED (15-DAY)		OT	NVSC2020CA083797		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Off Label Use; Treatment Failure	Neoral		S	Subcutaneous	Unk	Novartis
	Neoral		S	Subcutaneous	Unk	Novartis
	Cyclosporine		S	Unknown	Unk	Novartis
	Methotrexate		S	Oral	20 Mg	Not Reported
	Methotrexate		S	Subcutaneous	Unk	Not Reported
	Apo-Leflunomide		S	Unknown	Unk	Not Reported
	Actemra		S	Intravenous drip	8 Mg/Kg, Unk	Not Reported
	Actemra		S	Intravenous drip	8 Mg/Kg, Unk	Not Reported
	Enbrel		S	Subcutaneous	500 Mg (Every 1 Weeks)	Not Reported
	Orencia		S	Subcutaneous	125 Mg	Not Reported
	Plaquenil		S	Oral	Unk	Not Reported
	Plaquenil		S	Subcutaneous	Unk	Not Reported
	Remicade		S	Intravenous drip	3 Mg/Kg,Unk	Not Reported
	Xeljanz		C	Oral	5 Mg (2 Every 1 Day)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585786	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2020M1031634		29 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Transient Ischaemic Attack; Treatment Failure	Atorvastatin			S	Unknown	Unk		Not Reported
	Clopidogrel			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585836	EXPEDITED (15-DAY)		OT	NVSC2020CA083902			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug	Methotrexate Sodium			S	Subcutaneous	20 Mg, (16 Years)		Not Reported
	Neoral			S	Oral	20 Mg (16 Years)		Novartis

Ineffective; Rheumatoid Arthritis	Enbrel		S	Subcutaneous	50 Mg (3 Months)	Not Reported
	Plaquenil		S	Oral	20 Mg (16 Years)	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	3.0 Mg/Kg (12 Years)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585895	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025893		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Drug Ineffective; Fall	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17586685	NON-EXPEDITED		DE	NVSC2020US084340		59 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malignant Melanoma Stage Iv; Malignant Neoplasm Progression	Dabrafenib			S	Oral	150 Mg, Bid		Novartis
	Dabrafenib			S				Novartis
	Trametinib			S	Oral	2 Mg, Qd		Not Reported
	Trametinib			S				Not Reported
	Hydroxychloroquine			S	Oral	400- 600 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Oral	600 Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17586974	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025902			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Orencia			S	Endocervical			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17587086	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024299		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Hydroxychloroquine	S	Unknown	20 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	300 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Risedronate	S	Oral	35 Milligram, Qwk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17587200	EXPEDITED (15-DAY)		DS, HO, OT	CA-PFIZER INC-2018488256		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme Increased; Ileus; Intestinal Obstruction; Musculoskeletal Stiffness; Off Label Use; Product Use In Unapproved Indication; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Milligram, Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo Hydroxyquine			S	Unknown	Unk		Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
	Prednisone	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17587396	EXPEDITED (15-DAY)		OT	NVSC2020CA066714		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Cyclosporine			S	Subcutaneous	Unk		Novartis
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Xeljanz Xr			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17587547	EXPEDITED (15-DAY)		OT	NVSC2020CA084494		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Neoral			S	Subcutaneous			Novartis
	Neoral			S	Unknown	Unk		Novartis
	Cyclosporine			S	Unknown			Novartis
	Leflunomide			S	Unknown	20.0 Mg, Qd		Not Reported
	Leflunomide			S				Not Reported
	Methotrexate Sodium			S	Subcutaneous	20.0 Mg		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Qw		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Qw		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3.0 Mg		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	5 Mg, Bid		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Cimzia			C	Subcutaneous	200.0 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17587578	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2020M1031637		50 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Disease Progression; Pseudomonas Infection; Pulmonary Fibrosis; Skin Ulcer; Treatment Failure	Azathioprine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	60 Milligram		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Dapsone			S	Unknown	Unk		Mylan
	Rituximab			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17587783	NON-EXPEDITED			NVSC2020US083346			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Xolair			S	Unknown	Unk, Q4w		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Hydroxyzine			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown			Not Reported
	Dupilumab			S	Unknown	Unk		Not Reported
	Dapsone			S	Unknown	Unk		Not Reported
	Lycor			S	Unknown			Not Reported
	Singulair			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C	Unknown	1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17588061	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020126107			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Rheumatoid Arthritis	Methotrexate Sodium	S	Unknown	Pfizer
	Enbrel	S	Unknown	Pfizer
	Sulfasalazine	S	Unknown	Pfizer
	Codeine	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17588436	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025383		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Subcutaneous	750 Milligram		Bristol Myers Squibb
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituximab			S	Intravenous drip	2000 Milligram		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17588455	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025435			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Orencia		S	Subcutaneous		Bristol Myers Squibb
	Actemra		S	Subcutaneous		Not Reported
	Arava		S	Unknown		Not Reported
	Cimzia		S	Subcutaneous		Not Reported
	Desoximetasone		S	Oral		Not Reported
	Enbrel		S	Unknown		Not Reported
	Folic Acid		S	Unknown	5 Milligram	Not Reported
	Fosamax		S	Unknown		Not Reported
	Humira		S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown	500 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17588457	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025454			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulphate			S	Oral	400 Milligram		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17588491	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026044		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Amlodipine Besilate			S	Oral	5 Milligram, Qd		Not Reported
	Asacol			S	Unknown	800 Mg 3 Every 2 Days		Not Reported
	Diamicron			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Gliclazide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous drip	1000 Milligram		Not Reported
	Atacand Plus			C	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			C	Unknown	Unk		Not Reported
	Diphenhydramine			C	Oral	50 Milligram		Not Reported
	Ebastine			C	Unknown	Unk		Not Reported
	Ferrous Gluconate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	100 Milligram		Not Reported
	Methylprednisolone Acetate			C	Intra-articular	Unk		Not Reported
	Rosuvastatin Calcium			C	Unknown	Unk		Not Reported

	Tylenol		C	Unknown	Unk	Not Reported
	Vitamin D3		C	Unknown	Unk	Not Reported
	Acetaminophen		C	Oral	650 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17591609	DIRECT	Y	LT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Haemodialysis; Intensive Care	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	11480152	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20150902732			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Back Pain; C-Reactive Protein Abnormal; Cataract; Cerebrovascular Accident; Crying; Deformity; Depression; Disability; Drug Ineffective; Dry Eye; Dyspnoea; Fatigue; Fine Motor Skill Dysfunction; Foot Deformity; Gait Disturbance; Hand Deformity; Hepatic Enzyme Increased; Hepatitis C; Hypokinesia; Impaired Healing; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Muscle Atrophy; Muscle Spasms;	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Senokot			C	Unknown			Not Reported
	Coversyl			C	Unknown			Not Reported
	Percocet			C	Unknown			Not Reported
	Ativan			C	Sublingual	Night At Bedtime		Not Reported
	Lovastatin			C	Unknown			Not Reported
	Flexeril			C	Oral			Not Reported
	Flexeril			C	Oral			Not Reported
	Cyclobenzaprine Hydrochloride			C	Subcutaneous			Not Reported
	Acetaminophen W/Oxycodone Hydrochloride			C				Not Reported

Musculoskeletal Disorder; Musculoskeletal Pain; Myalgia; Papule; Peripheral Swelling; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Arthritis; Rheumatoid Nodule; Shoulder Deformity; Surgical Failure; Swelling; Weight Decreased; Wrist Deformity

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	12883751	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013303		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Knee Arthroplasty; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Apo-Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Apo-Prednisone			S	Unknown			Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	15 Unk, Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

	Plaquenil /00072602/			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	12893895	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20150810477		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Nasopharyngitis; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Arava			C				Not Reported
	Codeine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	13059056	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015753		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Hepatotoxicity; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Leflunomide			S	Oral	10 Mg, Unk		Apotex
	Leflunomide			S		20 Mg, Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S				Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Unk		Apotex
	Apo-Leflunomide			S	Oral	10 Mg, Unk		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Sulfasalazine			S	Unknown	2 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	2 G, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	10 Mg, Unk		Not Reported
	Arava			S	Unknown	20 Mg, Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Celebrex			S				Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	2.5 Mg, Unk		Not Reported
	Orencia			S	Subcutaneous	250 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	13244457	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006744			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia;	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	20.0 Mg, Qd		Apotex

Rash; Visual Impairment	Methotrexate	S	Subcutaneous	15 Mg, Q.Wk.		Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Qd		Not Reported
	Sulfasalazine	S	Oral	1 G, Qd		Not Reported
	Actemra	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Orencia	S	Unknown			Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	13519394	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038533		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Prescribed Underdose	Orencia			S	Subcutaneous	150 Mg, Qmo		Bristol Myers Squibb
	Sulfasalasin			S	Unknown	500 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Not Reported
	Celebrex			S	Unknown	200 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naprosyn [Naproxen]			S	Unknown	500 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	14628698	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-037929		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Event; Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Off Label Use; Therapeutic Product Effect Decreased	Orencia	S	Intravenous (not otherwise specified)	Unk	Bristol Myers Squibb
	Orencia	S	Unknown	Unk	Bristol Myers Squibb
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	1 Df, Qwk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Q2wk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Every One Day	Not Reported
	Xeljanz	S	Oral	5 Milligram, Q2wk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Lyrica	S	Oral	Unk	Not Reported
	Lyrica	S	Unknown	Unk	Not Reported
	Prednisone	C	Oral	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Codeine	C	Unknown	Unk	Not Reported
	Lyrica	C	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram, Q2wk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	15049818	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015756		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Nodule; Rheumatoid Arthritis	Leflunomide			S	Oral			Apotex
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	15076377	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP016010			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	15400431	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083976		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cataract; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Metformin Hydrochloride			S	Unknown	500 Mg, Bid		Bristol Myers Squibb
	Desoximetasone			S	Unknown			Not Reported
	Docosahexaenoic Acid;Eicosapentaenoic Acid			C	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Altace			C	Unknown	5 Mg, Qd		Not Reported
	Asa			C	Unknown	81 Mg, Qd		Not Reported
	Folic Acid			C	Unknown	1 Df, Unk		Not Reported
	Methotrexate			C	Oral	15 Mg, Qd		Not Reported
	Omega 3 [Fish Oil;Tocopherol]			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Unknown	20 Mg, Qd		Not Reported
	Rosuvastatin Calcium			C	Unknown			Not Reported
	Vitamin D3			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	15978351	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013839		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein	Orencia			S	Unknown			Bristol Myers Squibb

Increased; Cataract; Drug Ineffective; Laboratory Test Abnormal; Off Label Use; Red Blood Cell Sedimentation Rate Abnormal	Celebrex	S	Oral	200 Milligram, Q12h	Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Q12h	Not Reported
	Arava	C	Unknown	20 Milligram, Qd	Not Reported
	Xeljanz	S	Oral	5 Milligram, Q12h	Not Reported
	Rituximab	S	Intravenous drip		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	16108792	EXPEDITED (15-DAY)		HO, LT	PHHY2019CA062642			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S				Novartis
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S				Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S				Not Reported

Enbrel	S	Unknown	Unk		Not Reported
Enbrel	S	Subcutaneous	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Humira	S	Unknown	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Remicade	S	Unknown	Unk		Not Reported
Remicade	S				Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk		Not Reported
Sulfasalazine	S				Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	16889106	EXPEDITED (15-DAY)		OT	CA-SA-2019SA271272			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Response Decreased	Arava			S	Unknown			Sanofi
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Xeljanz			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17064857	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190827902		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastritis; Headache; Nausea; Pain; Platelet Count Increased; Systemic Lupus Erythematosus	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Plaquenil /00072602/	S	Oral	Dose Doubled In Jan-2020	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17335679	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-HORIZON-PRE-0036-2020			Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Growth Restriction; Maternal Exposure During Pregnancy; No Adverse Event; Oligohydramnios; Premature Baby	Prednisone			S	Transplacental	Unk		Not Reported
	Omeprazole			S		Unk		Not Reported
	Bisulepin			S	Transplacental	Unk		Not Reported
	Aminomethylbenzoic Acid			S	Transplacental	Unk		Not Reported
	Dexamethasone			S	Transplacental	Unk		Not Reported
	Dexamethasone			S	Transplacental	Unk		Not Reported
	Vitamin D [Colecalciferol]			S	Transplacental	Unk		Not Reported
	Folic Acid			S	Transplacental	Unk		Not Reported
	Cefixime			S	Transplacental	Unk		Not Reported
	Paracetamol			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Privigen			S	Transplacental	Unk		Not Reported
	Privigen			S	Transplacental	Unk		Not Reported
	Ornidazole			S	Transplacental	Unk		Not Reported
	Magnesium Lactate			S	Transplacental	Unk		Not Reported
	Vitamin K Nos			S	Transplacental	Unk		Not Reported
	Bisoprolol Fumarate			S	Transplacental	Unk		Not Reported
	Vulmizolin			S	Transplacental	Unk		Not Reported
	Vitamin B Complex			S		Unk		Not Reported
	Calcium Carbonate			S	Transplacental	Unk		Not Reported
	Potassium Chloride			S	Transplacental	Unk		Not Reported
	Fluconazole			S	Transplacental	Unk		Not Reported
	Penicillin G [Benzylpenicillin Sodium]			S	Transplacental	Unk		Not Reported

	Flebogamma Dif [Immunoglobulin Human Normal]	S	Transplacental	Unk	Not Reported
	Hydrocortisone	S	Transplacental	Unk	Not Reported
	Methylprednisolone	S	Transplacental	Unk	Not Reported
	Methylprednisolone	S	Transplacental	Unk	Not Reported
	Nadroparine	S	Transplacental	Unk	Not Reported
	Etamsylate	S	Transplacental	Unk	Not Reported
	Cefotaxime	S	Transplacental	Unk	Not Reported
	Cefotaxime	S	Transplacental	Unk	Not Reported
	Metoprolol Tartrate	S	Transplacental	Unk	Not Reported
	Albumin	S	Transplacental	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17530878	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202002001243			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Hypersensitivity; Nausea; Rheumatoid Arthritis; Urticaria; Vertigo; Weight Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Celebrex			C		Unk		Not Reported
	Tylenol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17552501	EXPEDITED (15-DAY)		OT	GB-CELLTRION INC.-2020GB020489			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dermatomyositis; Disease Progression; Product Use In Unapproved Indication; Pseudomonas Infection;	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Dapsone			S	Unknown	Unk		Not Reported

Pulmonary Fibrosis; Skin Ulcer; Treatment Failure	Mycophenolate	S	Unknown			Not Reported
	Azathioprine	S	Unknown	Unk		Not Reported
	Prednisolone	S	Unknown	60 Milligram		Not Reported
	Prednisolone	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17570310	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068426			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17578248	EXPEDITED (15-DAY)		HO, LT, OT	PT-MYLANLABS-2020M1031689		50 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Tamponade; Cardiogenic Shock; Cardiomegaly; Concomitant Disease Aggravated; Dyspnoea Exertional; Dyspnoea Paroxysmal Nocturnal; Electrocardiogram Qrs Complex Abnormal; Heart Sounds Abnormal;	Bosentan			S	Oral	250 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	5 Mg, Qd		Mylan
	Mycophenolate Mofetil			S	Unknown	2.5 G, Qd		Mylan
	Remodulin			S	Subcutaneous	0.046 Mg, Q1hour		Mylan
	Remodulin			S	Subcutaneous	0.046 Mg, Q1hour		Mylan
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Mylan
	Riociguat			C	Unknown	6 Mg, Qd		Mylan

Oedema Peripheral; Pericardial Effusion; Pericardiotomy; Pleural Effusion; Prohormone Brain Natriuretic Peptide Increased; Rales; Serositis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17578988	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024680			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17588707	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025879		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Stress	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

Methotrexate	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Mefenamic Acid	C	Unknown			Not Reported
Prednisone	C	Oral	6 Milligram, Qd		Not Reported
Tylenol	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17588868	EXPEDITED (15-DAY)		DS, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0830		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme Increased; Ileus; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapy Non-Responder	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Apo Hydroxyquine	S	Unknown	Not Reported
	Apo-Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17588873	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1542			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17588875	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1543			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug	Methotrexate (Trade Name			S	Unknown			Not Reported

Intolerance; Rheumatoid Arthritis	Unknown) Enbrel	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Actemra	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17588876	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1554			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17588922	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17589340	EXPEDITED (15-DAY)		HO, OT	US-ORION CORPORATION ORION PHARMA-20_00008751		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Infective; Bartonella Test Positive; Cat Scratch Disease; Device Dislocation; Pneumonia	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590071	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-241501		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Microsporidia Infection	Hydroxychloroquine			S	Unknown	Unk		Sun
	Hydroxychloroquine			S				Sun
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported

	Mycophenolate Mofetil	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590112	EXPEDITED (15-DAY)		HO	CA-SA-2020SA075289			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Off Label Use	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd (1 Everyday)		Sanofi
	Leflunomide			S	Unknown	10 Mg, Qd, Tablet (1 Every 1 Day)		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw (1 Every 1 Weeks)		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	80 Mg/Kg		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow., Solution Subcutaneous		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Qw		Not Reported
	Orencia			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590113	EXPEDITED (15-DAY)		OT	CA-SA-2020SA075134			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Stiffness; Joint Swelling; Pain; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Atorvastatin Calcium			S				Not Reported
	Leflunomide			S				Sanofi

	Pregabalin	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Sulfasalazine	S		Not Reported
	Trichlormethiazide	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590114	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA075343			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Hypersensitivity; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Hydroxychloroquine			S	Oral	400 Mg		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Leflunomide			S		10 Mg		Sanofi
	Leflunomide			S		10 Mg		Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S		15 Mg		Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Sulfasalazine			S	Oral	1 G		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg		Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous	125 Mg, Qw		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Rituximab			S		Unk		Not Reported
	Prednisone			C		10 Mg		Not Reported
	Prednisone			C		5 Unk		Not Reported
	Simponi			C	Subcutaneous			Not Reported

Xeljanz	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590131	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009143		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Gait Disturbance; Wrist Surgery	Meloxicam			S	Unknown	Unk		Apotex
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590361	EXPEDITED (15-DAY)		OT	CA-SA-2020SA075141			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S				Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Golimumab			S				Not Reported
	Humira			S				Not Reported
	Infliximab			S				Not Reported
	Otezla			S				Not Reported
	Acetaminophen			C				Not Reported
	Advair			C				Not Reported
	Allopurinol			C				Not Reported
	Atrovent Hfa			C				Not Reported
	Codeine			C				Not Reported
	Cyclobenzaprine Hydrochloride			C				Not Reported
	Dilaudid			C				Not Reported
	Hydromorphone Hydrochloride			C				Not Reported
	Ibuprofen			C				Not Reported
	Leucovorin Calcium			C				Not Reported
	Nexium [Esomeprazole Sodium]			C				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C				Not Reported

	Sulfasalazine	C	Not Reported
	Ventolin Hfa	C	Not Reported
	Xeljanz	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590363	EXPEDITED (15-DAY)		OT	CA-SA-2020SA076294			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S	Oral	20 Mg, Qd		Not Reported
	Actemra			S				Not Reported
	Lyrica			S	Oral	150 Mg, Bid		Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590399	EXPEDITED (15-DAY)		OT	CA-SA-2020SA076538		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine Sulfate			S		200 Mg, Qd		Sanofi
	Arava			S				Sanofi
	Sodium Aurothiomalate			S		Unk		Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Leflunomide			S		Unk		Sanofi
	Methotrexate			S	Oral	25 Mg, Qd		Not Reported
	Myochrysine			S	Intramuscular	25 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590401	EXPEDITED (15-DAY)		OT	CA-SA-2020SA076268			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Sanofi
	Leflunomide			S	Unknown	10 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	15 Mg		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590669	EXPEDITED (15-DAY)		OT	US-AMNEAL PHARMACEUTICALS-2020-AMRX-00900		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Cyclophosphamide			S	Unknown	21-Day Cycle, 4 Cycles		Amneal
	Docetaxel			S	Unknown	21-Day Cycle, 4 Cycles		Amneal
	Anastrozole			S	Unknown	21-Day Cycle, 4 Cycles)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	7.1 Mg/Kg Real Body Weight, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590700	EXPEDITED (15-DAY)		HO	US-GYP-000097		30 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatitis; Herpes Simplex; Trichomoniasis	Prednisone	S	Unknown	5 Mg Daily	Geneyork Pharma
	Hydroxychloroquine	S	Unknown	200 Mg Twice Daily	Not Reported
	Metronidazole	S	Oral		Not Reported
	Paracetamol	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591184	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026344		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Orencia			S	Endocervical			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	2 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591627	DIRECT		HO			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Folliculitis; Oral Disorder; Pharyngeal Disorder; Skin Swelling; Therapy Cessation; Urticaria; Urticaria	Hydroxychloroquine (Plaquenil)			S	Oral			Not Reported
	Pravastatin			C				Not Reported
	Fosomax			C				Not Reported
	Prempro			C				Not Reported
	Premarin			C				Not Reported

	Sipronlactone	C	Not Reported
	Minoxidil	C	Not Reported
	Doxycycline	C	Not Reported
	Omeprazole	C	Not Reported
	Singular	C	Not Reported
	Ventolin	C	Not Reported
	Azelastine	C	Not Reported
	B-Complex	C	Not Reported
	Triple Omega Fish Oil	C	Not Reported
	Calcium	C	Not Reported
	Vit. D-3	C	Not Reported
	Evening Primrose	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591702	EXPEDITED (15-DAY)		OT	NVSC2020CA083830		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Methotrexate			S	Unknown	25 Mg, Unknown		Not Reported
	Tacrolimus			S	Oral	2 Mg, Q12h		Novartis
	Tacrolimus			S	Oral	3 Mg, Q12h		Novartis
	Leflunomide			S	Unknown	20 Mg, Unknown		Not Reported
	Neoral			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Unknown		Not Reported
	Certolizumab Pegol			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxyquinoline Sulfate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rapamune			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591728	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA085589		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S				Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591840	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026340			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591841	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026360		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Orencia			S	Endocervical			Bristol Myers Squibb
	Actemra			S	Unknown	1 Dosage Form		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Calcium			C	Unknown	500 Milligram, Qd		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown	Unk, Bid		Not Reported
	Ergocalciferol			C	Unknown	Unk, Qwk		Not Reported
	Estradiol			C	Unknown	0.6 Percent, Tid		Not Reported
	Estrogel			C	Unknown	0.6 Percent, Tid		Not Reported
	Furosemide			C	Unknown	40 Milligram, Qd		Not Reported
	Gravol			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown	1500 Milligram, Qd		Not Reported

	Valsartan	C	Unknown	320 Milligram, Qd		Not Reported
	Xalatan	C	Ophthalmic	50 Microgram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591924	EXPEDITED (15-DAY)		OT	CA-SA-2020SA076466			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Hydroxychloroquine			S		200 Mg, Qd		Sanofi
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	25 Mg, Qw		Not Reported
	Leflunomide			S				Sanofi
	Enbrel			S		50 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591928	EXPEDITED (15-DAY)		OT	CA-SA-2020SA076322			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Pregabalin			S	Oral	150 Mg, Bid		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Actemra			S				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591942	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA085582			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris	S	Unknown	Unk		Novartis
	Ilaris	S				Novartis
	Leflunomide	S	Unknown	Unk		Not Reported
	Leflunomide	S				Not Reported
	Methotrexate	S	Intra-arterial	Unk		Not Reported
	Methotrexate	S				Not Reported
	Rituximab	S	Unknown	Unk		Not Reported
	Rituximab	S				Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Actemra	S				Not Reported
	Anakinra	S	Unknown	Unk		Not Reported
	Anakinra	S				Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Enbrel	S				Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Humira	S				Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S				Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia	S				Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade	S				Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Sulfasalazine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591972	NON-EXPEDITED			US-SA-2018SA048629			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Liver Function Test Increased	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S		Unk Unk,Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17592969	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068673		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Product Use Issue; Treatment Failure; Uveitis	Leflunomide			S		Unk		Sanofi
	Leflunomide			S				Sanofi
	Hydroxychloroquine			S	Subcutaneous	40 Mg		Sanofi
	Hydroxychloroquine			S				Sanofi
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S		20 Mg		Not Reported
	Methotrexate			S		10 Mg		Not Reported
	Kevzara			S				Sanofi
	Sulfasalazine			S				Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 G		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tocilizumab			S				Not Reported
	Tofacitinib			S				Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			C		10 Mg		Not Reported
	Rabeprazole Sodium			C		20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17593152	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026342			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qd		Not Reported
	Myochrysine			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17594000	EXPEDITED (15-DAY)		OT	NVSC2020CA083912		74 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Limb Deformity; Musculoskeletal Pain; Pain; Pain In Extremity; Pruritus; Rash; Squamous Cell Carcinoma Of Skin; Treatment Failure	Neoral			S	Unknown	125 Mg, Bid, (2 Every 1 Day)		Novartis
	Rituximab			S	Intravenous (not otherwise specified)	1 G, Unknown		Not Reported
	Arava			S	Unknown	20 Mg, Qd, (Every 1 Day)		Not Reported
	Azathioprine Sodium			S	Unknown	150 Mg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw, (1 Every 1 Week)		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	150 Mg, Tid, (3 Evey 1 Day)		Not Reported
	Methotrexate			S	Oral	1 Df, Qw, (1 Every 1 Week)		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid (2 Every 1		Not Reported

				Day)	
	Sulfasalazine	S	Oral	1 G, Bid, (2 Every 1 Day)	Not Reported
	Citalopram Hydrobromide	C	Unknown	40 Mg	Not Reported
	Citalopram Hydrobromide	C	Unknown	40 Mg, Qd (Every 1 Day)	Not Reported
	Citalopram Hydrobromide	C	Unknown	1 Df, Qw	Not Reported
	Prednisone	C	Unknown	10 Mg, Qd (Every 1 Day)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17594417	EXPEDITED (15-DAY)		DE, HO	NVSC2020CA085101		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Ilaris			S	Subcutaneous			Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported

Remicade	S	Unknown		Not Reported
Remicade	S			Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17594574	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022677			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colonic Abscess; Drug Ineffective; Pruritus	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	350 Milligram		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	40 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Enbrel			C	Unknown	50 Milligram		Not Reported
	Gold			C	Intramuscular	50 Milligram		Not Reported
	Leflunomide			C	Unknown	20 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2020	17431505	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1186390			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance	Hydroxychloroquine			S	Unknown			Teva

	Trametinib	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2020	17595044	EXPEDITED (15-DAY)		OT	IT-ACCORD-177503		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Furosemide			S				Accord
	Dabigatran			S	Oral			Not Reported
	Daparox			S				Not Reported
	Lamictal			S				Not Reported
	Plaquenil			S				Not Reported
	Valium			S				Not Reported
	Sotalol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2020	17595150	NON-EXPEDITED			NVSC2020US086178			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2020	17597821	DIRECT		DS			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Eye Disorder; Vascular Device User	Hydroxychloroquine	Y		S	Oral	Quantity:1 Tablet(S);		Unknown
	Orencia	Y		S	Intramuscular	Quantity:1 Injection(S);Other Frequency:Once A Week;		Er Squibb
	Heart Meds			C				Not Reported
	Diabetes Meds			C				Not Reported
	Inhalers			C				Not Reported
	Med For Migraines			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2020	17598592	DIRECT		DS			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Stiffness; Manufacturing Materials Issue; Product Complaint; Product Substitution Issue; Therapy Non-Responder	Hydroxychloroquine 200mg Tab			S				Dr Reddys
	Omeprazole			C				Not Reported
	Hydroxychloroquinine			C				Not Reported
	Clarinex			C				Not Reported
	Turmeric			C				Not Reported
	Iron			C				Not Reported
	Mvi			C				Not Reported
	Vitamind3			C				Not Reported
	Aleve			C				Not Reported
	Tylenol			C				Not Reported
	Pseudoephedrine			C				Not Reported
	Guaifenesin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	12351402	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2016GSK063971		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Eye Disorder; Gait Disturbance; Gait Inability; Joint Dislocation; Stomatitis	Voltaren			S	Unknown	Unk		Glaxosmithkline
	Cortisone			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Apo-Diclofenac			S		Unk		Not Reported
	Desoximetasone			S		Unk		Not Reported
	Diclofenac Potassium			S		Unk		Not Reported
	Remicade			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	12764755	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076425			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Disability; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme Increased; Ileus; Intestinal Obstruction; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapy Non-Responder; Wheelchair User	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	12767211	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-015691		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Synovitis; Tooth Loss	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Varicella Zoster Vaccine Live			S	Intravenous (not otherwise specified)			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			C	Oral	10 Milligram, Bid		Not Reported
	Xeljanz			C	Subcutaneous	Unk		Not Reported
	Desoximetasone			C	Oral	10 Milligram, Qd		Not Reported
	Desoximetasone			C	Oral	5 Milligram 2 Every 1 Day		Not Reported
	Zostavax			C	Subcutaneous	Unk		Not Reported
	Cortisone			C	Oral	10 Milligram, Qd		Not Reported
	Diclofenac			C	Subcutaneous	100 Milligram, Qd		Not Reported
	Voltaren Acti			C	Unknown	100 Milligram, Qd		Not Reported
	Cortisone Acetate			C	Subcutaneous			Not Reported

Desoximetasone	C	Subcutaneous			Not Reported
Diclofenac	C	Oral	50 Milligram, Bid		Not Reported
Diclofenac	C	Oral	100 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	12771269	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076855		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Synovitis; Tooth Loss	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Zostavax			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous	Unk		Not Reported
	Varicella Zoster Vaccine Live			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Diclofenac [Diclofenac Sodium]			C	Subcutaneous	100 Milligram		Not Reported

Diclofenac [Diclofenac Sodium]	C	Oral	5 Milligram, Bid		Not Reported
Cortisone	C	Oral	Unk		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Xeljanz	C	Oral	10 Milligram, Bid		Not Reported
Cortisone Acetate	C	Subcutaneous	Unk		Not Reported
Desoximetasone	C	Oral	5 Milligram, Bid		Not Reported
Desoximetasone	C	Oral	10 Milligram, Qd		Not Reported
Desoximetasone	C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	13251617	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006643			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Zostavax			S	Subcutaneous	Unk		Not Reported
	Zostavax			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Desoximetasone			C	Oral	Unk		Not Reported

	Diclofenac	C	Unknown	100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	13502224	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1253		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Haematoma; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Naprosyn			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	14547629	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-040466		28 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Sinusitis; Anaphylactic Shock; Anxiety; Bronchitis; Depression; Device Malfunction; Electric Shock; Faeces Soft; Fatigue; Gait Disturbance; Headache; Influenza Like Illness; Long Qt Syndrome; Mouth Ulceration; Nausea; Off Label Use; Pain; Productive Cough; Pyrexia; Seasonal Allergy; Secretion Discharge; Sinusitis; Tongue Ulceration; Upper	Abatacept			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Pantoloc [Pantoprazole]			C	Unknown	Unk		Not Reported
	Leucovorin [Folinic Acid]			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Ativan			C	Unknown	Unk		Not Reported

Respiratory Tract Infection
Bacterial

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	14918934	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043916		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Subcutaneous	750 Mg, Qwk		Bristol Myers Squibb
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Gram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Tid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	2000 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Parenteral	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	2000 Mg, Unk		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	2000 Milligram		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

	Actemra		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Tofacitinib		C	Unknown	Unk	Not Reported
	Xeljanz		C	Oral	5 Mg, Q2wk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	15551969	EXPEDITED (15-DAY)		OT	PHHY2018CA135990		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Psoriatic Arthropathy; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk (Solution)		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Apremilast			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unknown		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Infliximab			C	Unknown	Unk		Not Reported
	Penicillin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	16387991	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-029881		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated;	Lisinopril Tablet			S	Unknown	Unk		Aurobindo

Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Osteoarthritis; Pain; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Folic Acid	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	20 Milligram, Every Week	Not Reported
	Plaquenil	S	Oral	200 Milligram, Once A Day	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Once A Day	Not Reported
	Synthroid	S	Unknown	Unk	Not Reported
	Tecta	S	Oral	Unk	Not Reported
	Voltaren Sr	S	Oral	75 Milligram,As Required	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Two Times A Day	Not Reported
	Depo-Medrol	C	Intramuscular	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	16388028	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-029853		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Osteoarthritis; Pain; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Lisinopril Tablet			S	Unknown	Unk		Aurobindo
	Diclofenac Potassium			S	Oral	75 Milligram		Not Reported
	Diclofenac Potassium			S	Oral	75 Milligram, Two Times A Day		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Milligram, Every Week		Not Reported
	Plaquenil			S	Oral	200 Milligram, Once A Day		Not Reported
	Plaquenil			S	Oral	400 Milligram, Once A Day		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Once A Day		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Two Times A Day		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Tecta			S	Oral	Unk		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Two Times A Day		Not Reported

	Depo-Medrol	C	Intramuscular	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	16778008	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-025000		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown			Not Reported
	Cortisone			S	Oral			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Topicort			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sarilumab	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported
Atasol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	16792776	EXPEDITED (15-DAY)		OT	PHHY2019CA209333			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis; Drug Ineffective; Infection	Cosentyx			S	Unknown	150 Mg, Qw		Novartis
	Humira			S	Subcutaneous	40 Mg, Q2w		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported
	Plaquenil			S	Oral	200 Mg, Qd		Not Reported
	Arava			C	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			C	Oral	1 Df, Qw		Not Reported
	Prednisone			C	Oral	1 Df, Qd		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Q12h		Not Reported

Xeljanz	C	Oral	5 Mg, Q12h		Not Reported
Xeljanz	C	Oral	5 Mg, Q8h		Not Reported
Xeljanz	C	Oral	5 Mg, Q12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	16881443	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-28961		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Joint Swelling; Pneumonia; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown, Solution		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Remicade			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Single-Use Pre-Filled Syringe		Not Reported
	Cimzia			S	Unknown	Unknown, Single-Use Pre-Filled Syringe		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Rituximab			S	Unknown	Unknown		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unknown		Not Reported
	Xeljanz			S	Oral			Not Reported
	Lidocaine Hydrochloride			S	Subcutaneous	Unknown, Aerosol		Not Reported
	Lidocaine Hydrochloride			S	Subcutaneous	Unknown		Not Reported
	Cephalexin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17467057	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-008069		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Arthralgia; Arthritis; Arthropathy; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Creatinine Increased; Blood Parathyroid Hormone Decreased; Blood Pressure Systolic Increased; C-Reactive Protein Abnormal; Decreased Appetite; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Intolerance; Enthesopathy; Erythema; Fatigue; Fear Of Injection; General Physical Health Deterioration; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Insomnia; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Pain; Panniculitis; Peripheral Swelling;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Apo Ibuprofen			S	Oral	600 Milligram		Not Reported
	Alendronate Sodium			S	Unknown	70 Milligram		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Apremilast			S	Oral	30 Milligram, Bid		Not Reported
	Apremilast			S	Unknown	60 Milligram, Bid		Not Reported
	Apremilast			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Celebrex			S	Oral	200 Milligram, Bid		Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Codeine			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Cyclosporin			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Golimumab			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ibuprofen			S	Oral	600 Milligram, Every 1 Days		Not Reported

Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Infliximab	S	Intravenous (not otherwise specified)	400 Milligram	Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral	Unk, Qwk	Not Reported
	Motrin Children	S	Oral	600 Milligram	Not Reported
	Motrin Children	S	Unknown	6 Dosage Form, Qd	Not Reported
	Motrin Children	S	Oral	600 Milligram, Qd	Not Reported
	Motrin Children	S	Oral	Unk Milligram, Qd	Not Reported
	Otezla	S	Oral	30 Milligram, Bid	Not Reported
	Otezla	S	Unknown		Not Reported
	Otezla	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
	Rituximab	S	Unknown	1000 Milligram, Bid	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Sulfamethoxazole	S	Oral	600 Milligram	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown	360 Milligram	Not Reported
	Ustekinumab	S	Subcutaneous	Unk	Not Reported
	Etanercept	S	Subcutaneous	Unk	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Etanercept	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Apo-Cyclosporine	S	Unknown	Unk	Not Reported

Apo-Cyclosporine	S	Oral	Unk	Not Reported
Acide Folique	C	Unknown		Not Reported
Actonel	C	Oral	35 Milligram, Qwk	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk	Not Reported
Colchicine	C	Unknown	0.6 Milligram	Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Febuxostat	C	Unknown	80 Milligram, Bid	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gravol	C	Unknown		Not Reported
Methotrexate Sodium	C	Oral	Unk, Qwk	Not Reported
Mogadon	C	Unknown	5 Milligram	Not Reported
Naproxen	C	Unknown	500 Milligram	Not Reported
Nitrazepam	C	Oral	Unk	Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Oxycodone	C	Unknown	10 Milligram	Not Reported
Oxycodone	C	Unknown	40 Milligram	Not Reported
Oxycodone Hydrochloride	C	Unknown	10 Milligram	Not Reported
Oxycodone Hydrochloride	C	Unknown	40 Milligram	Not Reported
Oxyneo	C	Unknown	10 Milligram	Not Reported
Oxyneo	C	Unknown	40 Milligram	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Uloric	C	Oral	8 Milligram, Bid	Not Reported
Uloric	C	Unknown	Unk	Not Reported
Uloric	C	Unknown	80 Milligram, Bid	Not Reported
Vitamin D3	C	Oral	200 International Unit	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17493046	EXPEDITED (15-DAY)		OT	GB-SUN PHARMACEUTICAL		29 YR	Male	GBR

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2020R1-238891

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Transient Ischaemic Attack; Treatment Failure	Atorvastatin			S	Unknown	Unk		Sun
	Warfarin			S	Unknown	Unk		Taro
	Clopidogrel			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17581926	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA083381		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Ilaris			S	Unknown			Novartis
	Ilaris			S				Novartis
	Ilaris			S	Subcutaneous			Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Rituximab			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S			Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17584606	EXPEDITED (15-DAY)		OT	NVSC2020US082743		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Microsporidia Infection; Product Use In Unapproved Indication	Mycophenolate Mofetil			S	Unknown	3 G, Qd		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596866	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-015777		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Furosemide			S	Unknown	Unk		Aurobindo
	Dabigatran Etexilate			S	Oral	300 Milligram, Once A Day		Not Reported
	Daparox			S	Unknown	Unk		Not Reported
	Lamictal			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Valium			S	Unknown	Unk		Not Reported
	Sotalol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596878	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068447			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Arava			S	Oral	20 Mg, Qd		Sanofi
	Actemra			S				Not Reported
	Enbrel			S		Unk		Not Reported
	Hydroxychloroquine			S	Oral	600 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Folic Acid			C		1 Df, Qw		Not Reported
	Xeljanz			C		5 Mg, Bid		Not Reported
	Xeljanz			C	Oral	5 Mg, Qd		Not Reported
	Prednisone			C				Not Reported
	Simponi			C	Subcutaneous	Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596898	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068448			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Arava			S		Unk		Sanofi
	Desoximetasone			S		Unk		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Folic Acid			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Cetrizine			S		Unk		Not Reported

Cimzia	S		Unk		Not Reported
Etanercept	S		Unk		Not Reported
Fosamax	S		Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Orencia	S	Subcutaneous	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596904	EXPEDITED (15-DAY)		OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-241793		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	8.22 Milligram/Kilogram		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596948	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068521		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased	Arava			S	Unknown			Sanofi
	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Methotrexate			S	Unknown	20.0 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown	Dosage Form: Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
	Rituxan	S	Unknown	Dosage Form: Solution Intravenous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596953	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068456			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Leflunomide			S		20 Mg		Sanofi
	Methotrexate			S		15 Mg, Qw		Not Reported
	Plaquenil			S		200 Mg, Bid		Sanofi
	Actemra			S		567 Mg, Qm		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596954	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068451			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Leflunomide			S				Sanofi
	Hydroxychloroquine			S		400 Mg, Qd		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596980	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1580			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596997	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068694			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dactylitis; Dermatitis Psoriasiform; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Hypoacusis; Nausea; Psoriatic Arthropathy; Therapeutic Product Effect Incomplete; Vomiting	Leflunomide			S		10 Mg		Sanofi
	Leflunomide			S		Unk, Qd		Sanofi
	Plaquenil			S		200 Mg, Bid		Sanofi
	Cosentyx			S		150 Mg, Q4w		Not Reported
	Humira			S		400 Mg In 7 Years		Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Prednisone			S				Not Reported
	Cymbalta			C		60 Mg, Qd		Not Reported
	Esomeprazole Magnesium;Naproxen			C	Oral			Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596998	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068558		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Leflunomide	S	Unknown	Unk	Sanofi
	Hydroxychloroquine	S		Unk	Sanofi
	Sulfasalazine	S		Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Sanofi
	Mefenamic Acid	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	40 Mg	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S		50 Mg, Qw	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S		Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Tocilizumab	S		Unk	Not Reported
	Xeljanz	S	Oral	10 Mg, Qd	Not Reported
	Synthroid	C		Unk	Not Reported
	Rabeprazole Sodium	C		Unk	Not Reported
	Folic Acid	C		Unk	Not Reported
	Metformin	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596999	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068621			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia;	Arava			S		Unk		Sanofi

Condition Aggravated; Drug Ineffective; Joint Swelling; Joint Swelling; Musculoskeletal Disorder; Nasopharyngitis; Neutropenia; Platelet Count Decreased; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Hydroxychloroquine	S		200 Mg, Qd	Sanofi
	Leflunomide	S	Unknown	20 Mg, Qd	Sanofi
	Plaquenil	S	Unknown	200 Mg, Qd	Sanofi
	Plaquenil	S	Unknown	Unk	Sanofi
	Enbrel	S		Unk	Not Reported
	Orencia	S		Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Qd	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Advil [Ibuprofen]	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Ketorolac	C		Unk	Not Reported
	Methotrexate	C	Unknown	20 Mg, Qw	Not Reported
	Naproxen	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597002	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068605			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Arava			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Sulfasalazine			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597003	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068651			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S		20 Mg, Qd		Sanofi
	Actemra			S				Not Reported
	Enbrel			S		25 Mg, Qow		Not Reported

Humira	S	Subcutaneous	40 Mg, Qow		Not Reported
Methotrexate	S		20 Mg, Qow		Not Reported
Orencia	S				Not Reported
Plaquenil	S		200 Mg, Bid		Sanofi
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Q6w		Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Bupropion	C				Not Reported
Sulfasalazine	C				Not Reported
Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597009	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068702			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspepsia; Food Intolerance; Hepatotoxicity; Rash; Rheumatoid Arthritis	Leflunomide			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Imuran [Azathioprine]			C		Unk		Not Reported
	Methotrexate			C		Unk Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597010	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068717		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea;	Leflunomide			S		Unk		Sanofi

Renal Mass; Vomiting	Allopurinol	S		Unk	Not Reported
	Folic Acid	S			Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Sanofi
	Prednisone	S		Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Naproxen	S		Unk	Not Reported
	Methotrexate	S		Unk	Not Reported
	Oxycodone Hydrochloride	S		Unk	Not Reported
	Azathioprine	S		Unk	Not Reported
	Ciclosporin	S			Not Reported
	Medroxyprogesterone Acetate	S		Unk	Not Reported
	Etanercept	S		25 Mg ,Qw	Not Reported
	Infliximab	S		400 Mg	Not Reported
	Rituximab	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597077	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1212448		54 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Headache; Palpitations	Risedronate Monosodique			S	Oral	35 Mg		Teva
	Plaquenil			S	Oral	1 Dosageform		Not Reported
	Cortancyl 20 Mg, Comprime			S	Oral			Not Reported
	Pantoprazole			C				Not Reported
	Izalgi 500 Mg/25 Mg, Gelule			C		500 Mg/25 Mg,		Not Reported
	Levothyrox 75 Microgrammes, Comprime Secable			C				Not Reported
	Diffu K, Gelule			C				Not Reported
	Atorvastatine			C				Not Reported
	Clopidogrel (Chlorhydrate De)			C				Not Reported
	Procoralan 5 Mg, Comprime Pellicule			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597242	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025396		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Bone Disorder; Drug Hypersensitivity; Drug Ineffective; Infection; Rash; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Cefazolin			S	Intramuscular			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Naproxen			C	Unknown	500 Milligram, 2 Every 1 Day		Not Reported
	Viread			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597342	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068726		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Balance Disorder; Cardiac Disorder; Coronary Artery Bypass; Dermatitis	Arava			S				Sanofi
	Gold Bond			S				Sanofi
	Humira			S	Subcutaneous			Not Reported

Allergic; Drug Hypersensitivity; Foot Deformity; Hand Deformity; Infection; Irritable Bowel Syndrome; Lung Neoplasm Malignant; Pain In Extremity; Surgery; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Toe Amputation	Methotrexate	S	Oral	10 Mg	Not Reported
	Plaquenil	S			Sanofi
	Arnica Montana	C			Not Reported
	Asa	C			Not Reported
	Calcium	C			Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597343	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068740			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Leflunomide			S		1 Df (1 Every 1 Days)		Sanofi
	Hydroxychloroquine			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S		500 Mg, Bid		Not Reported
	Xeljanz			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Lyrica			C				Not Reported
	Naproxen			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597347	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068725			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthrodesis; Drug Ineffective; Empyema; Foot Deformity; Hand Deformity; Joint Effusion; Joint Stiffness; Limb	Leflunomide			S		20 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Urethral	20 Mg, Qd		Sanofi
	Ibuprofen			S	Unknown	400 Mg		Not Reported

Operation; Musculoskeletal Stiffness; Nodule; Pneumonia; Rheumatoid Arthritis; Scar; Toe Operation	Methotrexate	S		25 Mg, Qw	Not Reported
	Methotrexate	S		25 Mg, Qw	Not Reported
	Methotrexate	S		25 Mg, Qw	Not Reported
	Sulfasalazine	S		2000 Mg, Qd	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Calcium	C		1200 Mg	Not Reported
	Ergocalciferol	C		2000 Iu, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597348	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068745		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Diarrhoea; Dyspepsia; Nodule; Osteoarthritis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S		25 Mg, Qw		Not Reported
	Sulfasalazine			S		1000 Mg, Bid		Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597350	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068748			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S		Unk		Sanofi
	Bacitracin			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Neomycin Sulfate			S		Unk		Not Reported
	Polymyxin B Sulfate			S		Unk		Not Reported

	Actemra		S	Subcutaneous	Unk	Not Reported
	Prednisone		C	Intramuscular		Not Reported
	Xeljanz		C	Oral	10 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597351	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068446		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Arava			S		Unk Unk, Qd		Sanofi
	Meloxicam			S		Unk		Not Reported
	Methotrexate			S				Not Reported
	Plaquenil			S				Sanofi
	Prednisone			S		5 Mg, Qd		Not Reported
	Sulfasalazine			S				Not Reported
	Paracetamol			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597410	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068817			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Fatigue; Hand Deformity; Infection; Pain; Therapy Non-Responder	Leflunomide			S	Unknown	20.0 Mg, Qd		Sanofi
	Celecoxib			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400.0 Mg, Qd		Sanofi
	Toradol			S	Unknown			Not Reported
	Methotrexate			C	Unknown	25.0 Mg, Qw		Not Reported
	Sulfasalazine			C		2.0 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597412	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068814		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Off Label Use; Pulmonary Fibrosis; Treatment Failure	Arava			S		Unk		Sanofi
	Desoximetasone			S	Oral	Unk		Sanofi
	Desoximetasone			S		Unk		Sanofi
	Leflunomide			S		1 Df, Qd		Sanofi
	Plaquenil			S		Unk		Sanofi
	Prednisone			S		Unk		Not Reported
	Hydroxychloroquine			S		200 Mg, Qd		Sanofi
	Hydroxychloroquine			S				Sanofi
	Methotrexate			S		Unk		Not Reported
	Methotrexate			S				Not Reported
	Enbrel			S		1 Df, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597474	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068888			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Joint Stiffness; Joint Swelling; Pruritus; Psoriasis	Leflunomide			S		1 Df, Qd		Sanofi
	Plaquenil			S		300 Mg, Qd		Sanofi
	Cimzia			S	Subcutaneous	Unk (Subcutaneous Solution)		Not Reported
	Alendronate Sodium			C	Oral	70 Mg		Not Reported
	Atenolol			C		3 Df		Not Reported
	Certolizumab Pegol			C	Subcutaneous	Unk		Not Reported
	Chlordiazepoxide;Clidinium Bromide			C	Oral	Unk		Not Reported
	Esomeprazole Magnesium			C	Oral	40 Mg		Not Reported

Trihydrate Hydrochlorothiazide	C	Oral	25 Mg, Qd		Not Reported
Lorazepam	C	Oral	1 Mg, Qd		Not Reported
Methotrexate	C		Unk		Not Reported
Sulfasalazine	C	Oral	Unk		Not Reported
Trimebutine	C		1 Df, Q12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597475	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068908			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Steatosis; Interstitial Lung Disease; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	15 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow, Solution Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597476	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068846			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Joint Swelling; Rheumatoid Arthritis; Synovitis; X-Ray Abnormal	Leflunomide			S	Unknown			Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Sanofi
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Cimzia			S	Subcutaneous	200 Mg		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

Enbrel	S	Unknown	50 Mg		Not Reported
Enbrel	S	Unknown	50 Mg, Qw		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Humira	S	Subcutaneous	40 Mg		Not Reported
Simponi	S	Subcutaneous			Not Reported
Xeljanz	C		5 Mg, Bid		Not Reported
Xeljanz	C		11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597487	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068893			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Finger Deformity; Hand Deformity; Peripheral Swelling; Peripheral Swelling; Rheumatoid Arthritis	Leflunomide			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597495	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA069320		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Leflunomide			S	Unknown			Sanofi
	Hydroxychloroquine			S				Sanofi
	Naproxen Sodium			S		Unk		Not Reported
	Prednisone			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Orencia			S				Not Reported
	Xeljanz			S				Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported

	Hydroxychloroquine Sulfate			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597496	EXPEDITED (15-DAY)		OT	CA-SA-2020SA069110			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Leflunomide			S				Sanofi
	Actemra			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Total Daily Dose 40 Mg		Not Reported
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597501	EXPEDITED (15-DAY)		OT	CA-SA-2020SA069115			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Ill-Defined Disorder; Neuropathy Peripheral; Stomatitis	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Hydroxychloroquine			S				Sanofi
	Sulfasalazine			S				Not Reported
	Tocilizumab			S				Not Reported
	Tofacitinib			S				Not Reported
	Xeljanz			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597502	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA069085		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Multiple Fractures; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S		Unk		Sanofi
	Actemra			S		Unk		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate			S				Not Reported
	Naproxen			S				Not Reported
	Naproxen Sodium			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S				Not Reported
	Prednisone Acetate			S				Not Reported
	Tocilizumab			S				Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Folic Acid			C		Unk		Not Reported
	Hydroxychloroquine Sulphate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597503	EXPEDITED (15-DAY)		OT	CA-SA-2020SA069113		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Peripheral Swelling; Rheumatoid Arthritis; Stress	Leflunomide			S	Unknown			Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	2.5 Mg, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597507	EXPEDITED (15-DAY)		OT	CA-SA-2020SA069114			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Intolerance; Finger Deformity; Foot Deformity; Gait Disturbance; Infection; Pancytopenia	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Humira			S	Subcutaneous	40 Mg 1 Every 2 Weeks		Not Reported
	Methotrexate			S	Oral	7.5 Mg 1 Every 1 Weeks		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597724	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA085875			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism	Ilaris			S	Unknown			Novartis
	Ilaris			S				Novartis
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Orencia	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597887	EXPEDITED (15-DAY)		HO	CA-SA-2020SA069360		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Naproxen Sodium			S				Not Reported
	Prednisone			S				Not Reported
	Methotrexate			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S				Not Reported
	Actemra			S				Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17598089	EXPEDITED (15-DAY)		DS, OT	CA-GLAXOSMITHKLINE-CA2020050982		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Malaise;	Diclofenac Sodium			S	Oral	75 Mg, Bid		Glaxosmithkline
	Diclofenac Sodium			S	Oral	75 Mg, Bid		Glaxosmithkline

Osteoarthritis; Pain; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Diclofenac Potassium	S	Oral	75 Mg, Prn	Glaxosmithkline
	Pantoprazole	S	Unknown	Unk	Glaxosmithkline
	Pantoprazole	S	Oral	Unk	Glaxosmithkline
	Folic Acid	S	Unknown	Unk	Glaxosmithkline
	Voltaren (Diclofenac Sodium)	S	Oral	75 Mg, Bid	Glaxosmithkline
	Apo - Diclo (Diclofenac Sodium)	S	Oral	75 Mg, Bid	Not Reported
	Apo Lisinopril	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Mg, Qd	Not Reported
	Lisinopril	S	Unknown	Unk	Not Reported
	Lisinopril Dihydrate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg, Qw	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2 G, Qd	Not Reported
	Synthroid	S	Oral	Unk	Not Reported
	Tecta	S	Oral	Unk	Not Reported
	Xeljanz	S	Oral	10 Mg, Qd	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Depo-Medrol	C	Intramuscular	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17598887	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA1495			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Exfoliative Rash; Fatigue; Hepatitis; Myositis; Off Label Use; Pruritus; Pyrexia; Swelling; Urticaria; Visual Impairment	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Prednisone	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17599129	EXPEDITED (15-DAY)		OT	CA-ROCHE-2571299		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17599148	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2020126926			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Dry Skin; Emphysema; Hypoaesthesia; Joint Injury; Joint Swelling; Nausea; Off Label Use; Paraesthesia; Product Use	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk (10mg To 15mg)		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Unk		Pfizer

Issue; Psoriatic Arthropathy; Rash; Rheumatoid Nodule	Methotrexate Sodium	S	Oral	15 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Oral	15 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	30 Mg, Unk	Pfizer
	Sulfasalazine	S	Unknown	2 G, 1x/Day	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Sulfasalazine	S	Unknown	2 G, 1x/Day	Pfizer
	Sulfasalazine	S	Unknown	4 G, 1x/Day	Pfizer
	Sulfasalazine	S	Unknown	3 G, 1x/Day	Pfizer
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Cosentyx	S	Intramuscular	300 Mg, Unk	Not Reported
	Cosentyx	S	Oral	40 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Unk	Not Reported
	Leflunomide	C		20 Mg, Unk	Not Reported
	Leflunomide	C		10 Mg, Unk	Not Reported
	Leflunomide	C		20 Mg, Unk	Not Reported
	Tocilizumab	C	Subcutaneous	162 Mg, Weekly	Not Reported
	Abatacept	C	Subcutaneous	125 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17599397	NON-EXPEDITED		OT	US-APPCO PHARMA LLC-2082107			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stevens-Johnson Syndrome; Suspected Product Contamination	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17600334	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026570		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17600344	EXPEDITED (15-DAY)		OT	CA-SA-2020SA076298		80 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Arava			S	Unknown	Unk		Sanofi

Leflunomide	S	Unknown	Tablet		Sanofi
Methotrexate	S	Unknown	20 Mg, Qw		Not Reported
Sulfasalazine	S	Unknown			Not Reported
Actemra	S	Unknown			Not Reported
Enbrel	S	Unknown			Not Reported
Humira	S	Subcutaneous	Solution Subcutaneous		Not Reported
Orencia	S				Not Reported
Allopurinol	C	Unknown	200 Mg, Qd (1 Every 1 Day)		Not Reported
Prednisone	C		5 Mg, Bid		Not Reported
Prednisone	C		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17600442	EXPEDITED (15-DAY)		DS, HO, OT	CA-SA-2020SA076641			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting;	Hydroxychloroquine Sulfate			S	Oral	5 Mg, Qd		Sanofi
	Naproxen			S		Unk		Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			S	Oral	3 Mg Bid		Not Reported
	Prednisone			S	Oral	5 Mg Bid		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qw		Not Reported
	Naproxen Sodium			S		Unk		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Triamcinolone Acetonide			S		Unk (Suspension Intra-Articular)		Sanofi
	Triamcinolone Acetonide			S				Sanofi
	Triamcinolone Acetonide			S				Sanofi
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Qow		Not Reported

Wheelchair User	Enbrel	S	Subcutaneous	12.5 Mg, Qd	Not Reported
	Immunoglobulins Nos	S	Intravenous (not otherwise specified)	70 G	Not Reported
	Infliximab	S		5 Mg	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg, Qw	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Qm	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Qow	Not Reported
	Triamcinolone	S	Subcutaneous	25 Mg, Qow	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17600446	EXPEDITED (15-DAY)		DS, HO, OT	CA-SA-2020SA076650			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock;	Hydroxychloroquine Sulfate			S		5 Mg/Kg, Qd		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg/M2, Qw		Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Triamcinolone Acetonide			S	Unknown			Sanofi
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg		Not Reported
	Enbrel			S	Subcutaneous	25 Mg		Not Reported
	Intravenous Immunoglobulin			S	Intravenous (not otherwise specified)	70 G		Not Reported
	Infliximab			S	Unknown	5 Mg		Not Reported
	Infliximab			S	Intravenous (not	3 Mg/Kg, Qw		Not Reported

Synovitis; Underdose; Vomiting			otherwise specified)			
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Qm		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17600447	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA076649			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Hydroxychloroquine Sulfate			S	Oral	5.0 Mg/Kg, Qd		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg/M2, Qw		Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Triamcinolone Acetonide			S	Unknown			Sanofi
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S		5 Mg, Bid		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Qow		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Qw		Not Reported
	Enbrel			S		12.5 Mg, Qw		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg, Qw		Not Reported
	Infliximab			S		5 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Mg, Qm		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17600654	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Psoriatic Arthropathy; Synovitis	Infliximab			S	Unknown	Unknown		Not Reported
	Apremilast			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Solution		Not Reported
	Cimzia			S	Unknown	Unknown		Not Reported
	Cosentyx			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown, Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Otezla			S	Oral	Unknown		Not Reported
	Otezla			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous		Not Reported
	Rituximab			S	Unknown	Unknown		Not Reported
	Simponi			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Penicillin			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17601616	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-10007		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Etanercept			S	Unknown	Unknown		Not Reported

Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Arava	S	Unknown	Unknown	Not Reported
	Biaxin	S	Unknown	Unknown	Not Reported
	Celebrex	S	Unknown	Unknown	Not Reported
	Cephalexin Monohydrate	S	Unknown	Unknown	Not Reported
	Ciprofloxacin	S	Unknown	Unknown	Not Reported
	Clindamycin Phosphate	S	Unknown	Unknown	Not Reported
	Codeine	S	Unknown	Unknown	Not Reported
	Enalapril	S	Unknown	Unknown	Not Reported
	Fosamax	S	Unknown	Unknown	Not Reported
	Hctz	S	Unknown	Unknown	Not Reported
	Hydralazine Hydrochloride	S	Unknown	Unknown	Not Reported
	Levaquin	S	Unknown	Unknown	Not Reported
	Losartan	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Metoprolol Tartrate	S	Unknown	Unknown	Not Reported
	Moxifloxacin Hydrochloride	S	Unknown	Unknown	Not Reported
	Pantoprazole Magnesium	S	Unknown	Unknown	Not Reported
	Pariet	S	Unknown	Unknown	Not Reported
	Penicillin G [Benzylpenicillin]	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Cipro [Ciprofloxacin]	C	Unknown	Unknown	Not Reported
	Esomeprazole	C	Unknown	Unknown	Not Reported
	Gold	C	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unknown	Not Reported
	Iron Sucrose	C	Unknown	Unknown	Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17602693	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026610		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17605425	DIRECT	Y	DE, LT			87 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Test Positive; Cough; Electrocardiogram Qt Prolonged; Urine Odour Abnormal	Hydroxychloroquine			S				Not Reported
	Azithromycin 250 Mg Tablet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	13350239	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP008095		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities;	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Apo-Prednisone			S	Unknown	2 Df, Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Prednisone			S	Unknown	2 Df, Q.O.D.		Not Reported

Neurogenic Bladder; Pollakiuria; Product Dose Omission; Product Dose Omission	Folic Acid	S	Unknown	Unk, Q.Wk.	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Qd	Apotex
	Actemra	S	Subcutaneous	162 Mg, Q.Wk.	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	281 Mg, 1 Every 4 Weeks	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	281 Mg	Not Reported
	Arava	S	Oral	20 Mg, Unk	Not Reported
	Cimzia	S	Subcutaneous	200 Mg, 1 Every 2 Weeks	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	25 Mg, Q.Wk.	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Plaquenil /00072602/	S	Oral	200 Mg, Bid	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Methotrexate	C	Unknown	25 Mg, Q.Wk.	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	15711597	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-113698		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Limb Discomfort; Off Label Use; Rash; Rheumatoid Arthritis; Urticaria	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Apo-Leflunomide			S	Oral	10 Milligram		Not Reported
	Cefazolin			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Milligram, Q2wk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Milligram, Q2wk		Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported

	Methotrexate	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Q2wk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
	Leflunomide	S	Oral	10 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Amlodipine	C	Unknown	Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Tofacitinib Citrate	C	Unknown	Unk	Not Reported
	Viread	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16079854	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05830		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Ankylosing Spondylitis; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Demyelination; Diabetes Mellitus; Drug	Infliximab			S	Unknown	Unknown		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Remicade			S	Intravenous (not	Unknown, Powder For		Not Reported

Hypersensitivity; Drug Ineffective; Impaired Gastric Emptying; Influenza; Off Label Use; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Treatment Failure			otherwise specified)	Solution Intravenous	
	Remicade	S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Duration 705	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Actemra	S	Unknown	Unknown	Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Ciclosporin	S	Unknown	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown. Solution	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Gold	S	Unknown	Unknown	Not Reported
	Gold	S	Intramuscular	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S			Not Reported
	Apo-Azathioprine	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported

	Rituximab		S	Unknown	Unknown	Not Reported
	Leflunomide		S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unknown	Not Reported
	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Anakinra		S	Unknown	Unknown	Not Reported
	Sodium Aurothiomalate		S	Intramuscular	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16079890	EXPEDITED (15-DAY)		DS, HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-06218		9 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Injection Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Dispensing Error; Product Use In	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown	Unknown		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Abatacept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported

Unapproved Indication; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Unknown	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Unknown	Not Reported
	Tocilizumab		S	Unknown	Unknown	Not Reported
	Tocilizumab		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16085223	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-06099		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Product Use Issue; Psoriasis; Red Blood Cell	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S				Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unknown, Solution		Not Reported
	Humira			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Prednisone		S	Oral		Not Reported
	Prednisone		S	Oral		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Triamcinolone		S	Other	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Oral		Not Reported
	Naproxen Sodium		S	Unknown	Unknown	Not Reported
	Apo-Naproxen		S	Unknown	Unknown	Not Reported
	Apo-Prednisone		S	Oral		Not Reported
	Triamcinolone Hexacetonide		C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16094586	EXPEDITED (15-DAY)		HO, OT	PHHY2019CA057581		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Qw		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk (Solution Subcutaneous)		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Naprosyn	C	Unknown	Unk		Not Reported
Erythromycin	C	Unknown	Unk		Not Reported
Morphine	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16443477	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2018-03342		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Sleep Disorder	Etanercept			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Certolizumab Pegol			S	Subcutaneous	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Cimzia			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown Solution		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Leflunomide			S				Not Reported
	Minocycline Hydrochloride			S	Unknown	Unknown		Not Reported
	Myochrysine			S	Intramuscular	Unknown Solution		Not Reported
	Myochrysine			S	Subcutaneous	Unknown		Not Reported
	Myochrysine			S	Parenteral	Unknown Solution Intramuscular		Not Reported
	Myochrysine			S	Unknown	Unknown		Not Reported

Myochrysine	S	Intramuscular	Unknown	Not Reported
Orencia	S	Unknown		Not Reported
Otezla	S	Oral	Unknown	Not Reported
Otezla	S	Unknown	Unknown	Not Reported
Rituxan	S	Intravenous drip	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Sirukumab	S	Unknown	Unknown	Not Reported
Sirukumab	S			Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unknown	Not Reported
Stelara	S	Subcutaneous	Unknown Solution	Not Reported
Stelara	S	Unknown	Unknown	Not Reported
Tocilizumab	S	Unknown	Unknown	Not Reported
Tofacitinib Citrate	S	Oral		Not Reported
Ustekinumab	S	Unknown	Unknown	Not Reported
Ustekinumab	S	Subcutaneous	Unknown	Not Reported
Xeljanz	S	Oral		Not Reported
Rituximab	S	Unknown	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituximab	S	Intravenous drip	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Unknown	Not Reported
Minocycline	S	Unknown	Unknown	Not Reported
Simponi	S	Subcutaneous	Unknown Solution	Not Reported
Simponi	S	Unknown	Unknown	Not Reported
Simponi	S	Subcutaneous	Unknown	Not Reported
Salazopyrin	S	Unknown	Unknown	Not Reported
Apremilast	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Sulfasalazine	S	Unknown	Unknown	Not Reported

Minocin	S	Unknown	Unknown		Not Reported
Methotrexate	C	Unknown	Unknown		Not Reported
Methotrexate	C	Unknown			Not Reported
Prednisone	C	Unknown	Unknown		Not Reported
Orencia	C	Unknown	Unknown		Not Reported
Orencia	C	Intravenous (not otherwise specified)	Unknown Powder For Solution		Not Reported
Orencia	C	Intravenous (not otherwise specified)	Unknown		Not Reported
Orencia	C	Unknown	Unknown		Not Reported
Orencia	C	Unknown			Not Reported
Plaquenil	C	Unknown	Unknown		Not Reported
Salazopyrin	C	Unknown	Unknown		Not Reported
Rheumatrex	C	Unknown	Unknown		Not Reported
Abatacept	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16788654	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA249407		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion	Diclofenac			S	Ophthalmic	Unk		Not Reported
	Sulfasalazine			S	Oral	500 Mg		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Q12h		Not Reported
	Topicort			S	Cutaneous	Unk		Sanofi
	Prednisone			S	Oral	Unk		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Sanofi
	Arava			S	Oral	Unk		Sanofi
	Cetirizine Hydrochloride			S	Unknown	10 Mg		Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine			S	Unknown	10 Mg		Not Reported

Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Hydrochloride				
	Cortisone Acetate	S	Topical	25 Mg	Not Reported
	Desoximetasone	S	Oral	Unk	Sanofi
	Folic Acid	S	Unknown	5 Mg	Not Reported
	Folic Acid	S	Unknown	1 Mg	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Qd	Sanofi
	Hydroxychloroquine	S	Unknown	Unk	Sanofi
	Hydroxychloroquine Sulfate	S	Oral	Unk	Sanofi
	Methotrexate	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate	S	Oral	25 Mg	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Sanofi
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Single Use Pre-Filled Syringe	Not Reported
	Cimzia	S	Subcutaneous	Single Use Pre-Filled Syringe	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Mg, Qd	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported

	Sulfathalidine	S	Oral	500 Mg	Not Reported
	Sulfathalidine	S	Oral	1000 Mg, Q12h	Not Reported
	Tofacitinib	S	Unknown	5 Mg, Q12h	Not Reported
	Tofacitinib Citrate	S	Unknown	5 Mg, Q12h	Not Reported
	Salazopyrin	C	Unknown	Unk	Not Reported
	Atasol [Paracetamol]	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16877937	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-28737		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Ciclosporin			S	Oral	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Imuran			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous	Unknown		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported

Apo-Leflunomide	S	Unknown		Not Reported
Certolizumab Pegol	S	Unknown		Not Reported
Gold	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Leflunomide	S	Unknown	Unknown	Not Reported
Lyrica	S	Unknown	Unknown	Not Reported
Mycophenolate Mofetil	S	Unknown	Unknown	Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Plaquenil	S	Unknown	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
Rituximab	S	Unknown	Unknown	Not Reported
Simponi	S	Unknown	Unknown, Solution Subcutaneous	Not Reported
Sodium Aurothiomalate	S	Unknown	Unknown	Not Reported
Tocilizumab	S	Unknown		Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous	Unknown	Not Reported
Xeljanz	S	Oral		Not Reported
Piroxicam	C	Unknown	Unknown	Not Reported
Prednisone	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16906473	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201909001003			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Response Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk,		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17194720	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-201912002914			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthma; Asthma; Chest Discomfort; Chest X-Ray Abnormal; Fall; Glaucoma; Joint Swelling; Macular Degeneration; Musculoskeletal Disorder; Musculoskeletal Pain; Nausea; Pneumonia; Pyrexia; Respiratory Tract Infection Bacterial; Retinal Toxicity; Rib Fracture; Therapeutic Response Shortened; Wheelchair User; White Blood Cell Count Increased	Hydroxychloroquine			S	Unknown	Unk, Plaquenil		Concordia
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Unk, Qd (1in 1d)		Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous	(1 In 2 Wk)		Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous	Unk, Weekly, (1 In 1 Wk),		Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous	Unk,Solution For Infusion In Pre-Filled Syringe		Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous	(1 In 1 Wk)		Not Reported
	Humira			S	Subcutaneous	Citrate Free		Not Reported
	Iron			C	Unknown	Unk		Not Reported
	Folic			C	Unknown	Unk		Not Reported
	Eliquis			C		Unk		Not Reported
	Prilosec			C		Unk		Not Reported
	Zantac			C		Unk		Not Reported
	Losartan			C		Unk		Not Reported
	Flexeril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17287199	EXPEDITED (15-DAY)		HO, LT, OT	CA-SAMSUNG BIOEPIS-SB-2020-00706			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported

Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use Issue; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Adalimumab	S	Subcutaneous	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown		Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Intravenous Immunoglobulin	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Intravenous Immunoglobulin	S	Intravenous (not otherwise specified)		Not Reported
	Intravenous Immunoglobulin	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported

Naproxen Sodium	S	Unknown	Unknown	Not Reported
Naproxen Sodium	S			Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Apo-Naproxen	S	Unknown	Unknown	Not Reported
Apo-Naproxen	S			Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Gamastan	S	Intramuscular		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Intravenous Immunoglobulin	S	Intravenous (not otherwise specified)		Not Reported
Intravenous Immunoglobulin	S	Intravenous (not otherwise specified)		Not Reported
Naproxen	S	Unknown	Unknown	Not Reported
Naproxen	S			Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Triamcinolone	S	Unknown	Unknown	Not Reported
Triamcinolone Acetonide	S	Intra-arterial	Unknown Suspension Intra Articular	Not Reported

Triamcinolone Acetonide	S	Intra-arterial	Unknown		Not Reported
Triamcinolone Acetonide	S	Unknown	Unknown		Not Reported
Triamcinolone Acetonide	S				Not Reported
Triamcinolone Hexacetonide	S	Unknown	Unknown		Not Reported
Folic Acid	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17521215	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1193557		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Paradoxical Drug Reaction; Sleep Disorder; Varicella Zoster Virus Infection	Hydroxychloroquine			S	Unknown			Teva
	Prednisone			S	Unknown	40 Milligram Daily;		Actavis
	Prednisone			S	Unknown	Tapered Down From 40 Mg/Day To 20 Mg/Day Over The Previous 4 Weeks		Actavis
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17557563	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318947			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Contraindicated Product Administered; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Simponi			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Celebrex		C	Unknown	Not Reported
	Lyrica		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17601958	EXPEDITED (15-DAY)		OT	CA-ROCHE-2571285			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17602357	NON-EXPEDITED			US-APPCO PHARMA LLC-2082131		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Synthroid			C	Unknown			Not Reported
	Januvia			C	Unknown			Not Reported
	Olmesartan Medoxomil And Hydrochlorothiazide			C	Unknown			Not Reported
	Troujeo			C	Unknown			Not Reported
	Ezetimibe			C	Unknown			Not Reported

	Vitamin B Complex			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17602740	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003001986			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17603176	EXPEDITED (15-DAY)		HO	NVSC2020CA086171		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17603214	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025877			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	20 Milligram		Not Reported

Treatment Failure; Vomiting	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605057	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA076608		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Nausea; Obesity; Septic Shock; Vomiting	Hydroxychloroquine Sulfate			S	Oral	5 Mg, Qd		Sanofi
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Triamcinolone Acetonide			S	Unknown			Sanofi
	Actemra			S	Intravenous (not otherwise specified)	280 Mg		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Mg		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605175	EXPEDITED (15-DAY)		OT	CA-SA-2019SA247463			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiomyopathy; Depression; Drug Ineffective; Drug Intolerance; Hypersensitivity; Myelopathy; Neuropathy Peripheral	Plaquenil	S		Unk	Sanofi
	Arava	S		Unk Unk, Unk	Sanofi
	Buprenorphine	C		10 Ug, Qd	Not Reported
	Xarelto	C		15 Mg, Qd	Not Reported
	Bisoprolol	C		12.5 Mg, Qd	Not Reported
	Lasix [Furosemide Sodium]	C		20 Mg (20mg Od/Q2days Depending On Need)	Not Reported
	Lasix [Furosemide Sodium]	C		Unk	Not Reported
	Vitamin D [Vitamin D Nos]	C		Unk	Not Reported
	Vitamin B12 Nos	C		Unk	Not Reported
	Vitamin B6	C		Unk	Not Reported
	Fish Oil	C		Unk Unk, Unk	Not Reported
	Calcium	C		Unk Unk, Unk	Not Reported
	Magnesium	C		Unk Unk, Unk	Not Reported
	Ramipril	C		12.5 Mg, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605363	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-09913		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alanine Aminotransferase Increased; Alopecia; Anxiety; Arthralgia; Aspartate Aminotransferase Increased; Asthenia; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis; Treatment Failure	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Simponi	S	Subcutaneous	Unknown	Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Cetirizine Hydrochloride	C	Unknown		Not Reported
	Cortisone	C	Unknown	Unknown	Not Reported
	Desoximetasone	C	Unknown	Unknown	Not Reported
	Gabapentin	C	Unknown		Not Reported
	Paracetamol	C	Unknown	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605416	DIRECT	Y	DE			41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Cardiac Arrest; Coronavirus Infection; Pneumonia; Renal Failure; Ventricular Tachycardia	Hydroxychloroquine			S	Oral		5 DAY	Not Reported
	Acetaminophen			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cisatricurium			C				Not Reported
	Doxycycline			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Pantoprazole			C				Not Reported
	Midazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605439	DIRECT	Y	LT			85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Tachycardia	Plaquenil			S	Oral	Other Frequency:Load - Then 200mg;		Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605541	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP009047			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatotoxicity; Rash	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk. (Therapy Duration 365 Unit Unspecified)		Not Reported
	Infliximab			S	Unknown	5 Mg/Kg, One Every Eight Week		Not Reported

	Methotrexate		S	Unknown	15 Mg, Unk	Not Reported
	Methotrexate		S	Subcutaneous	25 Mg, Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk, Qd	Not Reported
	Rituximab		C	Intravenous (not otherwise specified)	1 G, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605719	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-10553		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown Powder For Solution For Infusion		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Sulfasalazine			S	Oral	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Desoximetasone			C	Unknown	Unknown		Not Reported
	Methotrexate			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605780	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200331857		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cataract;	Remicade			S	Intravenous (not			Not Reported

Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased			otherwise specified)		
	Desoximetasone	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Metformin Hydrochloride	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Altace	C			Not Reported
	Asa	C			Not Reported
	Ergocalciferol	C			Not Reported
	Folic Acid	C			Not Reported
	Methotrexate	C	Oral		Not Reported
	Rosuvastatin Calcium	C			Not Reported
	D-Alpha Tocopherol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605804	EXPEDITED (15-DAY)		OT	US-APPCO PHARMA LLC-2082143			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17606206	EXPEDITED (15-DAY)		OT	IT-TEVA-2020-IT-1212925		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Furosemide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Teva
	Dabigatran Etexilate			S	Oral	300 Mg		Not Reported
	Daparox			S	Unknown			Not Reported
	Lamictal			S	Unknown			Not Reported
	Valium			S	Unknown			Not Reported
	Sotalol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17606630	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025455		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17606828	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA085981		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple	Cosentyx			S	Unknown	Unk		Novartis
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Oral	Unk Unk, Bid		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unknown		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	5 Mg, Bid		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira	S	Subcutaneous	40 Mg, Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Unknown	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Naproxen Sodium	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone Acetate	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	50 Mg, Bid	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	2 Df, Qd	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Folic Acid	C	Subcutaneous	Unk	Not Reported
	Insulin	C	Oral	Unk	Not Reported
	Metformin	C	Unknown	2 Df, Bid	Not Reported
	Plaquenil	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17608508	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-015824		54 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Headache; Palpitations	Risedronate			S	Oral	35 Milligram, Total		Aurobindo
	Plaquenil			S	Oral	1 Dosage Form, Once A Day		Not Reported
	Cortancyl			S	Oral	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Izalgi			C	Unknown	Unk		Not Reported
	Levothyrox			C	Unknown	Unk		Not Reported

	Diffu K		C	Unknown	Unk	Not Reported
	Atorvastatine		C	Unknown	Unk	Not Reported
	Clopidogrel Hydrochloride		C	Unknown	Unk	Not Reported
	Procoralan		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17611030	DIRECT	Y	DE, DS, LT			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Electrocardiogram Qt Prolonged; Pneumonia Viral	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	15626375	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555933-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Meloxicam			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Mobicox			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	15668473	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570151-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Off Label Use; Product Dose Omission; Rheumatoid Arthritis; Sensitivity To Weather Change; Toe Amputation	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Rituximab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Restasis			C				Not Reported
	Synthroid			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	15712088	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2588120-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Disorder	Orencia	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous drip		Not Reported
	Remicade	S	Intravenous drip	Powder For Solution Intravenous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	15712568	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587985-00		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Ill-Defined Disorder; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Toradol			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Prednisone	C	Unknown	Not Reported
	Tramadol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	15713594	EXPEDITED (15-DAY)		HO	CA-ABBVIE-18K-028-2583819-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	15738111	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594168-00		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported

Arava	S	Oral		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Meloxicam	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	15741654	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594158-00		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	16156007	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2728799-00		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Dermatitis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

Allergic; Investigation Abnormal; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Treatment Failure	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported
	Septra	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	16798598	EXPEDITED (15-DAY)		OT	CA-SA-2019SA250726		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus	Desoximetasone			S	Oral	Unk		Sanofi
	Desoximetasone			S	Oral	Unk		Sanofi
	Cortisone Acetate			S	Oral			Not Reported
	Diclofenac Sodium			S				Not Reported
	Topicort			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Prednisone			S				Not Reported
	Arava			S	Oral			Sanofi
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S				Not Reported
	Folic Acid			S		1 Mg		Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S		400 Mg, Qd		Sanofi
	Prednisone			S				Not Reported

Erythematosus; Wound	Pseudoephedrine Hydrochloride	S		Unk	Sanofi
	Sarilumab	S			Sanofi
	Sulfasalazine	S	Subcutaneous	1 G, Bid	Not Reported
	Sulfasalazine	S	Oral	1 G, Bid	Not Reported
	Desoximetasone	S			Sanofi
	Actemra	S			Not Reported
	Cortisone Acetate	S		Unk	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Methotrexate Sodium	S	Oral	25 Mg	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Reactine [Cetirizine Hydrochloride]	S		10 Mg, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S			Not Reported
	Leflunomide	C			Not Reported
	Atasol [Paracetamol]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	16805660	EXPEDITED (15-DAY)		DE	CA-TEVA-2019-CA-1108101		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Alendronate Sodium			S	Unknown			Actavis
	Atorvastatin Calcium			S	Unknown			Teva
	Ipratropium Bromide/Salbutamol Sulfate			S	Unknown			Teva

Metformin	S	Unknown	1000 Milligram Daily;		Not Reported
Omeprazole Magnesium	S	Oral			Teva
Furosemide	S	Unknown			Not Reported
Prednisone	S	Unknown	5 Milligram Daily;		Actavis
Flovent	S	Unknown			Not Reported
Lasix	S	Unknown			Not Reported
Nitrazadon	S	Unknown			Not Reported
Plaquenil	S	Unknown	300 Milligram Daily;		Not Reported
Salmeterol Xinafoate	S	Unknown			Not Reported
Tylenol	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17430893	NON-EXPEDITED			NVSC2020US036804			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
B-Lymphocyte Abnormalities; Foetal Exposure During Pregnancy	Rituximab			S	Transplacental	Maternal Dose: 500 Mg/M2		Not Reported
	Azathioprine			S	Transplacental	Maternal Dose: 100 Mg, Bid		Not Reported
	Prednisone			S	Transplacental	Maternal Dose: 5 Mg, Qd		Novartis
	Prednisone			S	Transplacental	Maternal Dose: 20 Mg, Qd		Novartis
	Prednisone			S	Transplacental	Maternal Dose: 1 Mg/Kg, Qd		Novartis
	Prednisone			S	Transplacental	Maternal Dose: 10 Mg, Qd		Novartis
	Hydroxychloroquine			S	Transplacental	Maternal Dose: Unknown		Not Reported
	Romiplostim			S	Transplacental	Maternal Dose: 3micrograms/Kg		Not Reported
	Romiplostim			S	Transplacental	Maternal Dose: 5 Micrograms/Kg		Not Reported
	Romiplostim			S	Transplacental	Maternal Dose: 1.5 Micrograms/Kg		Not Reported

	Romiplostim	S	Transplacental	Maternal Dose: 2 Microgram/Kg	Not Reported
	Romiplostim	S	Transplacental	Maternal Dose: 1microgram/Kg	Not Reported
	Dexamethasone	S	Transplacental	Maternal Dose: 10mg	Not Reported
	Dexamethasone	S	Transplacental	Maternal Dose: 40 Mg	Not Reported
	Belimumab	S	Transplacental	Maternal Dose: Unk, Qmo	Not Reported
	Iviglob-Ex	S	Transplacental	Maternal Dose: 500 Mg/Kg	Not Reported
	Iviglob-Ex	S	Transplacental	Maternal Dose: 1000 Mg/Kg	Not Reported
	Iviglob-Ex	S	Transplacental	Maternal Dose: 400 Mg/Kg	Not Reported
	Iviglob-Ex	S	Transplacental	Maternal Dose: 200 Mg/Kg	Not Reported
	Iviglob-Ex	S	Transplacental	Maternal Dose: 500 Mg/Kg, Tiw	Not Reported
	Iviglob-Ex	S	Transplacental	Maternal Dose: 500 Mg/Kg, Q2w	Not Reported
	Iviglob-Ex	S	Transplacental	Maternal Dose: 500 Mg/Kg, Tiw	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17432480	NON-EXPEDITED			NVSC2020US036797		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Product Use In Unapproved Indication	Rituximab			S	Intravenous (not otherwise specified)	500 Mg/M2		Not Reported
	Prednisone			S	Unknown	5 Mg, Qd		Novartis
	Prednisone			S	Unknown	20 Mg, Qd		Novartis
	Prednisone			S	Oral	1 Mg/Kg Qd		Novartis
	Prednisone			S	Unknown	10 Mg Qd		Novartis
	Azathioprine			S	Unknown	100 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Romiplostim	S	Subcutaneous	3 Micrograms/Kg	Not Reported
	Romiplostim	S	Unknown	5 Micrograms/Kg, Qw	Not Reported
	Romiplostim	S	Unknown	1.5 Micrograms/Kg, Qw	Not Reported
	Romiplostim	S	Unknown	2 Micrograms/Kg	Not Reported
	Romiplostim	S	Unknown	1 Microgram	Not Reported
	Belimumab	S	Unknown	Unk Unk, Qmo	Not Reported
	Dexamethasone	S	Unknown	10 Mg	Not Reported
	Dexamethasone	S	Oral	40 Mg	Not Reported
	Iviglob-Ex	S	Unknown	500 Mg/Kg	Not Reported
	Iviglob-Ex	S	Unknown	1000 Mg/Kg	Not Reported
	Iviglob-Ex	S	Unknown	400 Mg/Kg	Not Reported
	Iviglob-Ex	S	Unknown	200 Mg/Kg	Not Reported
	Iviglob-Ex	S	Unknown	500 Mg/Kg, Tiw	Not Reported
	Iviglob-Ex	S	Unknown	500 Mg/Kg, Q2w	Not Reported
	Iviglob-Ex	S	Unknown	500 Mg/Kg, Tiw	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17570316	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008939		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

			otherwise specified)		
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Unknown	Unk		Not Reported
Simponi	S	Unknown	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Enbrel	S	Unknown	Unk		Not Reported
Humira	S	Unknown	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Arthrotec	C	Oral	Unk		Not Reported
Arthrotec	C	Unknown	Unk		Not Reported
Azathioprine	C	Unknown	Unk		Not Reported
Ergocalciferol	C	Unknown	Unk		Not Reported
Gold	C	Unknown	Unk		Not Reported
Imuran /00001501/	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17571510	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008899			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17586904	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024281		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	680 Milligram, Qwk		Not Reported
	Actemra			S	Unknown	360 Milligram, Qmo		Not Reported
	Alendronic Acid			S	Unknown	70 Milligram, Qwk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	12 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram, Qwk		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, Qmo		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous drip	1000 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Ciclosporin			C	Unknown	150 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17608636	EXPEDITED (15-DAY)		OT	FR-FERRINGPH-2020FE01903		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Menopur			S	Subcutaneous			Ferring

	Plaquenil	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17608696	EXPEDITED (15-DAY)		OT	IT-BAXTER-2020BAX006523		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Diretif 10 Mg/Ml Soluzione Iniettabile			S	Unknown			Claris
	Dabigatran Etexilate			S	Oral			Not Reported
	Daparox			S	Unknown			Not Reported
	Lamictal			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Valium			S	Unknown			Not Reported
	Sotalol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17608746	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001933			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anterior Chamber Disorder; Blindness; Epstein-Barr Virus Infection; Eye Pain; Eye Pain; Intraocular Pressure Increased; Necrotising Retinitis; Ocular Hyperaemia; Retinal Detachment; Scleral Disorder; Uveitis; Varicella Zoster Virus Infection; Vision Blurred; Vitreous Floaters; Vitritis	Hydroxychloroquine			S	Unknown	200 Mg, Qd, Tablet		Concordia
	Prednisone			S	Unknown	10 Mg, Qd		Not Reported
	Cellcept			S	Unknown	1000 Mg, Bid		Not Reported
	Valacyclovir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17608765	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1216776			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Atorvastatin			S				Teva
	Methotrexate			S				Barr
	Plaquenil			S		400 Milligram Daily;		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Alprazolam			C				Not Reported
	Folic Acid			C				Not Reported
	Naprosyn			C		1000 Milligram Daily;		Not Reported
	Pantoloc			C				Not Reported
	Prednisone			C		5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17608937	EXPEDITED (15-DAY)		DS, HO, OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-000912			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congestive Cardiomyopathy; Dyspnoea; Left Ventricular Dysfunction	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Qd		Ipca
	Fexofenadine			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Novo Nordisk Pharms Novofem			C	Unknown	Unk		Not Reported
	Amitriptyline			C	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	Unk		Not Reported
	Clonazepam			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Tramadol			C	Unknown	Unk		Not Reported
	Hyoscine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17609386	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA086791		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Meperidine Hydrochloride			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Bisoprolol			S	Unknown	Unk		Novartis
	Bisoprolol			S	Unknown	Unk		Novartis
	Levofloxacin			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Qw		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Ceclor			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	200 Mg, Qd		Not Reported
	Demerol			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin Estolate			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	400 Mg		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Metronidazole			S	Unknown	5 Mg		Not Reported
	Norfloxacin			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17609994	EXPEDITED (15-DAY)		HO, OT	US-ACCORD-177659		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bartonella Test Positive; Cat Scratch Disease; Device Dislocation; Pneumonia	Methotrexate	S		Not Reported
	Hydroxychloroquine	S		Not Reported
	Rituximab	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17610209	EXPEDITED (15-DAY)		OT	IT-GLAXOSMITHKLINE-IT2020050661		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Lamotrigine			S	Unknown	Unk		Glaxosmithkline
	Furosemide			S	Unknown	Unk		Glaxosmithkline
	Daparox			S	Unknown	Unk		Glaxosmithkline
	Valium			S	Unknown	Unk		Glaxosmithkline
	Plaquenil			S	Unknown	Unk		Not Reported
	Dabigatran Etexilate			S	Oral	300 Mg, Qd		Not Reported
	Sotalol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17610630	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026351		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Infection; Rash; Rheumatoid Arthritis; Unevaluable Event; Urticaria	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Cefazolin			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Milligram, 1 Every 2 Weeks		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Milligram, 1 Every 2 Weeks		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 1 Every 2 Weeks		Not Reported

	Leflunomide	S	Oral	10 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, 1every One Week	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Amlodipine	C	Unknown	Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Tofacitinib Citrate	C	Unknown	Unk	Not Reported
	Viread	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17611049	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-09980			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Off Label Use; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported

Humira	S	Subcutaneous	Unknown		Not Reported
Hydroxychloroquine Phosphate	S	Unknown	Unknown		Not Reported
Methotrexate	S	Subcutaneous			Not Reported
Methylprednisolone	S	Unknown			Not Reported
Orencia	S	Unknown	Unknown		Not Reported
Plaquenil	S	Unknown	Unknown		Not Reported
Sulfasalazine	S	Unknown	Unknown		Not Reported
Xeljanz	S	Unknown	Unknown		Not Reported
Naproxen	C	Unknown	Unknown		Not Reported
Prednisone	C	Unknown	Unknown		Not Reported
Rituxan	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17611066	DIRECT	Y	DS, OT			76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Immunosuppressant Drug Level Increased	Plaquenil			S				Not Reported
	Azithromycin 500 Mg Iv			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17611141	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-10625			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Simponi	S	Subcutaneous	Unknown	Not Reported
	Sulfasalazine	S	Oral	Unknown	Not Reported
	Prednisone	C	Unknown		Not Reported
	Desoximetasone	C	Unknown	Unknown	Not Reported
	Methotrexate	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17611326	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20160600430			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17611609	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-10259			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disease Recurrence; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type	Etanercept			S	Unknown			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	Unknown		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unknown		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17611785	EXPEDITED (15-DAY)		OT	IT-VALIDUS PHARMACEUTICALS LLC-IT-2020VAL000236			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Furosemide			S	Unknown	Unk		Validus
	Plaquenil /00072603/			S	Unknown	Unk		Not Reported
	Lamotrigine			S	Unknown	Unk		Not Reported
	Diazepam			S	Unknown	Unk		Not Reported
	Sotalol Hydrochloride			S	Unknown	Unk		Not Reported
	Dabigatran			S	Oral	Unk		Not Reported
	Daparox /00830803/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17614765	DIRECT	Y	DE, LT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Cytokine Storm; Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral	Other Dose:400-200 Mg;		Not Reported
	Haldol			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Cefepime			C				Not Reported
	Chlorhexidine			C				Not Reported
	Cistaracurijm			C				Not Reported
	Docusate Sodium			C				Not Reported
	Exoxaparin			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Versed			C				Not Reported
	Propofol Continuous Infusion			C				Not Reported
	Pantoprazole			C				Not Reported
	Sennosides			C				Not Reported
	Sertraline			C				Not Reported
	Darunavir/Cobistat			C				Not Reported
	Apixaban			C				Not Reported
	Aspirin			C				Not Reported

	Donepezil	C	Not Reported
	Ketoconazole 2% Shampoo	C	Not Reported
	Nitroglycerin Sl	C	Not Reported
	Sertrraline	C	Not Reported
	Sevelamer	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	11626328	EXPEDITED (15-DAY)		DS, LT, OT	CA-UCBSA-2015032127		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment	Cimzia			S	Subcutaneous	Dosage Form: Solution		Not Reported
	Cimzia			S				Not Reported
	Cetirizine Hydrochloride			S		10 Mg, Unk		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Cetirizine Hydrochloride			S	Oral	10 Milligram, Once Daily (Qd)		Ucb
	Cetirizine Hydrochloride			S	Oral	10 Milligram		Ucb
	Cetirizine Hydrochloride			S		Unk		Ucb
	Zyrtec-D			S		10 Mg, Unk		Not Reported
	Zyrtec-D			S				Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S		Controlled Release Tablets		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S		25 Milligram, Ointment		Ucb
	Cirrus			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form: Lyophilized Powder		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S		5 Mg, Unk		Not Reported
	Folic Acid			S		5 Milligram		Not Reported
	Folic Acid			S		1 Milligram		Not Reported
	Folic Acid			S		1 Mg		Not Reported

Failure; Wound	Folic Acid	S		500 Milligram	Not Reported
	Prednisone	S	Oral	Dosage Form: Unknown	Not Reported
	Prednisone	S		Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S		Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Mg, Unk	Not Reported
	Sulfathalidine	S		Dosage Form: Unspecified	Not Reported
	Plaquenil	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
	Plaquenil	S	Oral	Unk Unk, Once Daily (Qd)	Not Reported
	Plaquenil	S	Oral	Unk Unk, Once Daily (Qd)	Not Reported
	Plaquenil	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Oral	20 Milligram	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
	Humira	S	Subcutaneous	40 Mg (0.8 Ml)	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate	S	Oral	20 Mg, Once Daily (Qd)	Not Reported
	Methotrexate	S	Oral	25 Mg, Unk	Not Reported
	Methotrexate	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
	Methotrexate	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
	Methotrexate	S	Oral	25 Mg, Unk	Not Reported
	Methotrexate	S		25 Mg, Unk	Not Reported

Sulfasalazine	S	Oral	1000 Mg, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Mg	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram, Once Daily (Qd)	Not Reported
Sulfasalazine	S		500 Milligram	Not Reported
Sulfasalazine	S		Unk	Not Reported
Apo-Folic Acid	S		5 Mg, Unk	Not Reported
Apo-Hydroxyquine	S		Unk	Not Reported
Apo-Prednisone	S		1 Milligram	Not Reported
Apo-Prednisone	S		5 Milligram	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S		Unk	Not Reported
Pseudoephedrine Hydrochloride	S		Unk	Not Reported
Pseudoephedrine Hydrochloride	S		1 Milligram	Not Reported
Pseudoephedrine Hydrochloride	S		25 Milligram	Not Reported
Pseudoephedrine Hydrochloride	S		10 Milligram	Not Reported
Pseudoephedrine Hydrochloride	S			Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S		Unk	Not Reported
Cortisone	S	Oral	25 Milligram	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Topicort	S	Cutaneous		Not Reported
Topicort	S	Subcutaneous	Unk	Not Reported

Leflunomide	S	Oral		Not Reported
Diclofenac Sodium	S		Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S		Unk Unk, Once Daily (Qd)	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk Unk, Once Daily (Qd)	Not Reported
Hydroxychloroquine Sulfate	S		400 Milligram, Once Daily (Qd)	Not Reported
Xeljanz	S		5 Mg, 2x/Day (Bid)	Not Reported
Xeljanz	S		Unk	Not Reported
Xeljanz	S		5 Mg, 2x/Day (Bid)	Not Reported
Xeljanz	S		Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Adalimumab	S		Unk	Not Reported
Paracetamol	S			Not Reported
Stelara	S			Not Reported
Actemra	S	Subcutaneous		Not Reported
Actemra	S			Not Reported
Cortisone	S	Oral		Not Reported
Cortisone Acetate	S	Oral	25 Milligram	Not Reported
Cortisone Acetate	S			Not Reported
Cortisone Acetate	S	Oral		Not Reported
Desoximetasone	S		Cutaneous Route	Not Reported
Desoximetasone	S	Oral		Not Reported
Diclofenac	S			Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
Enbrel	S			Not Reported
Humira	S	Sunconjunctival	40 Milligram	Not Reported
Humira	S	Sunconjunctival	Unk Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported

Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Rituxan	S	Intravesical		Not Reported
Sarilumab	S			Not Reported
Topicort	S	Oral		Not Reported
Topicort	S	Subcutaneous		Not Reported
Topicort	S	Oral		Not Reported
Topicort	S	Subcutaneous		Not Reported
Topicort	S		Unk	Not Reported
Topicort	S	Cutaneous		Not Reported
Hydrocortisone Acetate	S	Subcutaneous		Not Reported
Golimumab	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Leflunomide	S			Not Reported
Methotrexate	S	Intra-arterial	Unk	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Plaquenil	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Salazopyrin	C		Unk	Not Reported
Atasol	C		Unk	Not Reported
Tofacitinib Citrate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	13058846	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015717		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Rheumatoid Arthritis	Leflunomide	S	Unknown	Unk		Apotex
	Enbrel	S	Subcutaneous	25 Mg, B.I.Wk.		Not Reported
	Enbrel	S	Subcutaneous	25 Mg, B.I.Wk.		Not Reported
	Gold	S	Intramuscular			Not Reported
	Imuran /00001501/	S	Unknown			Not Reported
	Kineret	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Plaquenil /00072602/	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Anakinra	S	Subcutaneous	100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	13516082	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038066		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Off Label Use; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported

Imuran [Azathioprine]	S	Unknown	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	13669856	EXPEDITED (15-DAY)		DS, OT	CA-SA-2017SA106082		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S				Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Xeljanz			C	Oral	5 Mg,Bid		Not Reported
	Prednisone			C	Unknown	5 Mg,Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	14217330	EXPEDITED (15-DAY)		OT	CA-ROCHE-2025441		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Remicade			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	15620477	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2555079-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

Synovitis	Xeljanz	S	Oral	Not Reported
	Aleve	S	Oral	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Folic Acid	C		Not Reported
	Methotrexate	C	Unknown	Not Reported
	Plaquenil	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	15627967	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2558814-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	15635108	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2556219-00		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Blood Glucose Abnormal; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Dysphonia; Gait Disturbance; Hospitalisation; Joint Swelling; Loss Of Consciousness; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Rheumatoid Arthritis; Secretion Discharge; Sputum Discoloured; Therapeutic Product Effect Decreased; Thrombosis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Warfarin			S	Unknown			Not Reported
	Apo-Warfarin			S				Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported

	Prednisone		S	Unknown	Not Reported
	Amitriptyline		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	15728721	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1969198-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthralgia; Diarrhoea; Drug Hypersensitivity; Infection; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Methotrexate Sodium	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Apo-Leflunomide	S	Unknown			Not Reported
Apo-Leflunomide	S	Unknown			Not Reported
Apo-Leflunomide	S	Unknown			Not Reported
Apo-Hydroxyquine	S	Unknown	For 8 Years		Not Reported
Apo-Hydroxyquine	S	Unknown			Not Reported
Apo-Hydroxyquine	S	Unknown			Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown	For 8 Years		Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown			Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Vitamin D3	C				Not Reported
Imuran	C				Not Reported
Gold	C				Not Reported
Arthrotec	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	15732982	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17P-028-1858378-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Naproxen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	16337732	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-048239		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell	Ibuprofen			S	Oral	600 Milligram		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Alendronate Sodium			S	Unknown	70 Milligram		Not Reported
	Apo Ibuprofen			S	Oral			Not Reported
	Apremilast			S	Unknown	60 Milligram		Not Reported
	Apremilast			S	Unknown			Not Reported
	Apremilast			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported

Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Methotrexate	S	Unknown	15 Milligram,1 Every 1 Week	Not Reported
	Methotrexate	S	Unknown	17.5 Milligram, 4 Every1week	Not Reported
	Methotrexate	S	Unknown	12 Milligram,4every1week	Not Reported
	Methotrexate	S	Unknown	10 Milligram,4every 1week	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram,4every 1week	Not Reported
	Methotrexate	S	Unknown	70 Milligram,1every1week	Not Reported
	Otezla	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram,2every1day	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Endocervical		Not Reported
	Tocilizumab	S	Unknown	360 Milligram	Not Reported
	Tocilizumab	S	Unknown	680 Milligram	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	25 Milligram,2every1week	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Motrin [Ibuprofen]	S	Oral	600 Milligram, Qd	Not Reported
	Folic Acid	C	Unknown		Not Reported
	Gravol	C	Unknown		Not Reported
	Mogadon	C	Oral	5 Milligram	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C	Unknown		Not Reported
	Colchicine	C	Oral		Not Reported
	Dexilant	C	Unknown		Not Reported
	Febuxostat	C	Unknown		Not Reported

Nitrazepam	C	Unknown	5 Milligram		Not Reported
Oxycodone	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported
Uloric	C	Unknown	80 Milligram,2every1day		Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	16568503	EXPEDITED (15-DAY)		HO, OT	PHHY2019PL128630		35 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis Of Pregnancy; Erythema Nodosum; Maternal Exposure During Pregnancy; Normal Newborn	Erelzi			S	Intravenous (not otherwise specified)	50 Mg, Unk		Novartis
	Erelzi			S	Subcutaneous	50 Mg, Qw		Novartis
	Erelzi			S	Subcutaneous	50 Mg, Qw		Novartis
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Encorton			S	Unknown	10 Mg, Qd		Not Reported
	Encorton			S	Unknown	15 Mg, Qd		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Benepali			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	20 Mg, Qd		Not Reported
	Insulin			C	Unknown	Unk		Not Reported
	Metex			C	Subcutaneous	Unk (The Last Injection In Jan-2019)		Not Reported
	Metex			C	Subcutaneous	Unk (The Last Injection In Jan-2019)		Not Reported
	Folic			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	16820135	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-GSH201804-001105			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dizziness; Fatigue; Hepatomegaly; Malaise; Nausea; Pain In Extremity; Puncture Site Pain; Rash; Splenomegaly; Systemic Lupus Erythematosus; Vein Disorder; Vessel Puncture Site Bruise; Vessel Puncture Site Swelling	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Cerezyme			S	Intravenous drip	Dose/Unit: 3200.00 Frequency: Q2		Not Reported
	Cerezyme			S	Intravenous (not otherwise specified)	3200 Mg, Qow		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17566404	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318840		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre-Filled Syringe		Not Reported

	Hydroxychloroquine Sulfate	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Ergocalciferol	C			Not Reported
	Imuran /00001501/	C	Unknown		Not Reported
	Arthrotec	C	Unknown		Not Reported
	Vitamin D3	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17575062	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008919			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17609231	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002203			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17609364	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002205			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17609365	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002204			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17611781	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002279			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17611782	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002280			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia

	Dabrafenib	S	Oral	150 Mg, Bid		Not Reported
	Trametinib	S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17611783	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002281			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17613937	EXPEDITED (15-DAY)		OT	CA-ROCHE-2572186			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Localised Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17614080	EXPEDITED (15-DAY)		OT	AU-ADVANZ PHARMA-202003002074			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder; Organ Transplant; Unevaluable Event	Hydroxychloroquine			S	Unknown	Unk (For Over 30 Years)		Concordia
	Cellcept			S	Unknown	500 Mg, Tid (For 1.5 Years)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17614116	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-10342			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown, Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Rituximab			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17614240	EXPEDITED (15-DAY)		OT	CA-DRREDDYS-USA/CAN/20/0121425			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Stiffness; Joint Swelling; Pain; Rheumatoid Arthritis	Atorvastatin			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Lyrica			S	Unknown			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Trichlormethiazide	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17614467	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026601		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Orencia			S	Unknown			Bristol Myers Squibb
	Amlodipine Besilate			S	Oral	5 Milligram, Qd		Not Reported
	Asacol			S	Unknown	800 Milligram, Tid		Not Reported
	Diamicron			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Gliclazide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Oral	650 Milligram		Not Reported
	Atacand Plus			C	Unknown			Not Reported
	Bisoprolol Fumarate			C	Unknown			Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported
	Diphenhydramine			C	Oral	50 Milligram		Not Reported
	Ebastine			C	Unknown			Not Reported
	Ferrous Gluconate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported
	Vitamin D3	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17616393	DIRECT					63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Vertigo	Hydroxychloroquine 200 Mg Tablets			S	Oral	Quantity:180 Tablet(S);		Zydus Pharm
	Norvas			C				Not Reported
	Hctz			C				Not Reported
	Potassium Chloride			C				Not Reported
	Pantoprazole Sodium			C				Not Reported
	Predinsdone			C				Not Reported
	Pravastatin			C				Not Reported
	General Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17616524	EXPEDITED (15-DAY)		HO, OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-20-509		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Infective; Cat Scratch Disease; Complication Associated With Device	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Westward
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17616629	DIRECT		OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Rash; Visual Impairment	Hydroxychloroquine	S	Quantity:1 Tablet(S);		Sandoz
	Valsartan	C			Not Reported
	Metoprolol	C			Not Reported
	Atorvastatin	C			Not Reported
	Levothyroxine	C			Not Reported
	Hydrochlorothiazide	C			Not Reported
	Apsirin	C			Not Reported
	Women'S Silver Centrum	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17616815	DIRECT	Y	OT			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Hydroxychloroquine			S	Oral			American Health
	Atorvastatin 40mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17616895	EXPEDITED (15-DAY)		OT	NVSC2020GB089786		43 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Cutaneous Lupus Erythematosus; Cutaneous Lupus Erythematosus; Disease Progression; Madarosis; Mucosal Pain; Product Use In Unapproved Indication; Skin Plaque	Mycophenolate Mofetil			S	Unknown	1 G, Bid		Novartis
	Hydroxychloroquine			S	Transdermal	200 Mg, Qd		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17618200	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3348747-00		57 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Kaletra 100/25			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

	Zitromax	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17629156	DIRECT	Y				22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Hydroxychloroquine			S	Subcutaneous			Abbvie
	Humira			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	12994284	EXPEDITED (15-DAY)		OT	CA-SA-2016SA199672		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blastomycosis; Contraindicated Product Administered; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Knee Arthroplasty; Neoplasm Malignant; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	20 Mg,Qw		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Qw		Not Reported
	Sulfasalazine			C	Unknown	1 G, Bid		Not Reported
	Celebrex			C	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	13660454	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1724612US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Actonel			S	Unknown	35 Mg, Q Week		Allergan
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Leflunomide	S	Unknown	20 Mg, Qd		Not Reported
Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Unk		Not Reported
Plaquenil	S	Unknown	300 Mg, Qd		Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 G, Cyclical		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	300 Mg, Qd		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk Unk, Qd		Not Reported
Risedronic Acid	S	Unknown	Unk		Not Reported
Risedronic Acid	S	Unknown	35 Mg, Q Week		Not Reported
Risedronic Acid	S	Unknown	35 Mg, Q Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15108418	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2018CA0726		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Headache; Migraine; Respiratory Tract Infection; Therapeutic Product Effect Incomplete; Urinary Tract Infection	Kineret			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15619709	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555775-00		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Allergy To Vaccine; Diarrhoea; Drug Ineffective; Fall; Hypersensitivity; Larynx Irritation; Nausea; Product Use Issue; Pruritus; Rheumatoid Arthritis; Weight Decreased	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Zostavax	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15620439	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556971-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15621423	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2557292-00		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Contraindicated Product Administered; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Indomethacin			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Radioactive Gold			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Indometacin			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Cymbalta	C	Oral	Not Reported
	Folic Acid	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15621502	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557034-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Synovitis	Humira			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Tofacitinib	C			Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15622316	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557239-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Ineffective; Impaired Work Ability; Impaired Work Ability; Nasopharyngitis; Nasopharyngitis; Rheumatoid Arthritis; Rheumatoid Arthritis; Stress; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Celebrex			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Vioxx			S	Oral			Not Reported
	Vioxx			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Wellbutrin	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15629333	EXPEDITED (15-DAY)		CA, DS, HO, OT	CA-ABBVIE-18K-028-2557519-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre Filled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	Solution		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Foa-Solution		Not Reported
	Rituxan			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S				Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

Infliximab	S	Unknown	Not Reported
Certolizumab Pegol	S	Subcutaneous	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Arava	C	Oral	Not Reported
Orencia	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15662825	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-ABBVIE-18K-028-2569806-00		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Product Use In Unapproved Indication; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S				Not Reported
	Arava			S	Nasal			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Ilaris			S	Subcutaneous	Ilaris Single-Use Vial		Not Reported
	Ilaris			S	Subcutaneous	Ilaris Single-Use Vial		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Not Reported
Sodium Aurothiomalate	S		Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S		Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Rituximab	S		Not Reported
Gold	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S		Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S		Not Reported
Oxyquinoline Sulfate	S	Unknown	Not Reported
Oxyquinoline Sulfate	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15663251	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570496-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira	S	Subcutaneous	Not Reported
	Arava	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15717406	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587385-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; General Symptom; Neck Pain; Neck Surgery; Off Label Use; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Mobicox			C				Not Reported

	Remicade			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15811306	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2617216-00		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

	Apo-Leflunomide	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Alendronate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Alendronic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Ciclosporin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15930868	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2655637-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Kineret	S	Subcutaneous	Not Reported
	Desoximetasone	C		Not Reported
	Methotrexate	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Dexamethasone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15994348	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2674858-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Off Label Use; Osteoporosis; Pain; Rash; Surgery; Synovitis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	16079906	EXPEDITED (15-DAY)		HO, LT, OT	CA-SAMSUNG BIOEPIS-SB-2019-05955		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Intentional Product Use Issue; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Immune Globulin(Human)			S	Intravenous (not otherwise specified)			Not Reported
	Immune Globulin(Human)			S	Unknown	Unknown		Not Reported
	Immune Globulin(Human)			S	Intravenous (not otherwise specified)			Not Reported

In Unapproved Indication; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Naproxen	S	Unknown	Unknown	Not Reported
	Naproxen	S			Not Reported
	Naproxen Sodium	S	Unknown	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Unknown	Unknown	Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Triamcinolone	S	Other	Unknown	Not Reported
	Triamcinolone	S	Unknown	Unknown	Not Reported
	Triamcinolone	S	Subcutaneous		Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Unknown	Not Reported
	Triamcinolone Acetonide	S	Unknown	Unknown	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Unknown	Not Reported
	Apo-Naproxen	S	Unknown	Unknown	Not Reported
	Apo-Naproxen	S			Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Gamastan	S	Intramuscular	Liquid Intramuscular	Not Reported
	Tocilizumab	S	Unknown	Unknown	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported

	Folic Acid	C	Unknown	Unknown	Not Reported
	Triamcinolone Hexacetonide	C	Intra-articular	Unknown, Injectable Suspension	Not Reported
	Triamcinolone Hexacetonide	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	16444293	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2822475-00		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Cyclical		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Cyclical		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported

Actemra	S	Subcutaneous			Not Reported
Actonel	S	Unknown			Not Reported
Apo-Leflunomide	S	Oral	Cyclical		Not Reported
Apo-Leflunomide	S	Oral			Not Reported
Cimziasingle	S	Subcutaneous			Not Reported
Arava	S	Oral			Not Reported
Risedronate	S	Oral			Not Reported
Xeljanz	S	Oral			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Risedronate Sodium	S	Oral			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	16567681	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1074636			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Back Pain; Drug Ineffective; Enthesopathy; Hla Marker Study Positive; Pancytopenia; Spinal Pain; Spondyloarthropathy; Synovial Disorder	Diclofenac Sodium			S	Unknown	150 Milligram Daily;		Actavis
	Methotrexate			S	Unknown			Barr
	Naproxen			S	Unknown	1000 Milligram Daily;		Teva
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Hydroxychloroquine			C	Unknown	400 Milligram Daily;		Not Reported
	Leflunomide			C	Unknown			Not Reported
	Piroxicam			C	Unknown	20 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	16686320	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-21297		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Malaise; Nausea; Pain In Extremity; Peripheral Swelling; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis; Walking Aid User	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S				Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituximab			S	Intravenous (not	Unknown		Not Reported

			otherwise specified)		
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Atorvastatin	C	Unknown		Not Reported
	Atorvastatin	C	Unknown	Unknown	Not Reported
	Atorvastatin Calcium	C	Unknown	Unknown	Not Reported
	Pantoloc	C	Unknown	Enteric-Coated	Not Reported
	Pantoloc	C	Unknown		Not Reported
	Pantoloc	C	Unknown	Unknown	Not Reported
	Pantoprazole	C	Unknown	Unknown	Not Reported
	Pantoprazole Sodium Anhydrous	C	Unknown	Unknown	Not Reported
	Plaquenil	C	Oral		Not Reported
	Plaquenil	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	16687965	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210544		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Body Height Decreased; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Rheumatoid Arthritis	Arava			S		366 Unk		Sanofi
	Plaquenil			S		Unk		Sanofi
	Pregabalin			S		150 Mg		Not Reported
	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S		1000 Mg, Bid		Not Reported
	Orencia			S		Unk		Not Reported
	Orencia			S				Not Reported
	Xeljanz			S		Unk		Not Reported
	Rituxan			S		1000 Mg		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi			S	Intravenous (not otherwise specified)	1000 Unk		Not Reported

	Infliximab	S	Intravenous (not otherwise specified)	400 Mg	Not Reported
	Trazodone	C		200 Mg, Qd	Not Reported
	Lumigan Rc	C	Ophthalmic	1 Df, Qd	Not Reported
	Suphedrine [Pseudoephedrine Hydrochloride]	C		10 Mg, Qd	Not Reported
	Tylenol [Paracetamol]	C		Unk	Not Reported
	Tylenol [Paracetamol]	C		3000 Mg, Qd	Not Reported
	Valsartan	C		1 Df, Qd	Not Reported
	Valsartan	C		Unk	Not Reported
	Wellbutrin	C		300 Mg, Qd	Not Reported
	Esomeprazole	C		40 Mg, Qd	Not Reported
	Nexium [Esomeprazole Sodium]	C		40 Mg, Qd	Not Reported
	Tylenol Extra Strength	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	16720242	EXPEDITED (15-DAY)		OT	CA-SA-2019SA217291			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Ocular Toxicity; Rheumatoid Arthritis	Arava			S	Oral	10 Mg, Qd		Sanofi
	Diclofenac			S	Unknown	50 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd (Prior To 2011)		Sanofi
	Indometacin			S		50 Mg, (20 To 50 Mg) Tid		Not Reported
	Leflunomide			S	Oral	10 Mg, Qd (Prior To 2016)		Sanofi
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Methotrexate			S	Oral	15 Mg, (10 To 15 Mg) Qw (Prior To 2011)		Not Reported
	Naproxen			S	Unknown	500 Mg, Q6h		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported

	Xeljanz			S	Oral	5 Mg, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	16923698	EXPEDITED (15-DAY)		OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2019VAL000576			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Demerol			S	Unknown	Unk		Validus
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil /00072603/			S		Unk		Not Reported
	Diphenhydramine Hydrochloride			S		Unk		Not Reported
	Celecoxib			S	Oral	Unk		Not Reported
	Levofloxacin			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	250 Mg, Qd		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Imuran /00001502/			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5.0 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Unk		Not Reported
	Xeljanz			S	Oral	5 Unk		Not Reported
	Ezetrol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17199927	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3206389-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Perforation; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17559777	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008882			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17571111	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008956		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Q.O.Wk.		Apotex
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg, Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Enbrel			S				Not Reported

	Humira	S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Methotrexate	S	Oral	20 Mg, Q.Wk.		Not Reported
	Methotrexate	S	Oral	12.5 Mg, Unk		Not Reported
	Methotrexate	S	Oral	12.5 Mg, Qd		Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg, Qd		Not Reported
	Methotrexate	S				Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Mg, Unk, 1 Every 4 Weeks		Not Reported
	Orencia	S	Unknown	500 Mg, Unk, 1 Every 4 Weeks		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17575454	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008927		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Drug Ineffective; Drug Intolerance	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	200 Mg, Qd		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Arava			C	Unknown	20 Mg, Qd		Not Reported
	Simponi			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17611780	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002282			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17611784	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002283			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17611792	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002284			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17618992	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003001932			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Injury; Fatigue; Headache; Therapeutic Response Delayed; Therapeutic Response Shortened; Unevaluable Event	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Leflunomide			S	Unknown	Unk (Or, Dose, Frequency, Route Lot Number And Expiry Date Unknown)		Not Reported
	Actemra			S	Unknown	Unk (Suspended On 25-Feb-2020)		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Humira			C		Unk		Not Reported
	Enbrel			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

	Pantoloc			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17619006	EXPEDITED (15-DAY)		DS	CA-ADVANZ PHARMA-202003001934			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Diarrhoea; Drug Ineffective; Liver Disorder; Loss Of Personal Independence In Daily Activities; Oral Herpes	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			C				Not Reported
	Orencia			C				Not Reported
	Methotrexate			C		Unk		Not Reported
	Voltaren			C		Unk		Not Reported
	Leucovorin			C		Unk		Not Reported
	Iron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17620210	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009225		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Cataract; Contraindicated Product Administered; Dermatitis Allergic; Drug Ineffective; Drug Intolerance; Hepatotoxicity; Nasopharyngitis; Osteoarthritis; Pneumocystis Jirovecii Pneumonia; Rheumatoid Arthritis; Treatment Failure; Urticaria	Leflunomide			S	Oral	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported
	Sulfasalazine			S	Unknown	750 Mg, Qd		Not Reported
	Hydrochlorothiazide W/Lisinopril			C	Unknown	Unk		Not Reported

Hydrochlorothiazide W/Lisinopril Dihydrate	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	5 Mg, Qd		Not Reported
Rituxan	C	Unknown	Unk		Not Reported
Tylenol Extra Strength	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17620886	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA1493			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Ankylosing Spondylitis; Condition Aggravated; Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Impaired Gastric Emptying; Influenza; Off Label Use; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Treatment Failure	Kineret			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown	2.5 Mg 1 Every 2 Weeks		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17622122	EXPEDITED (15-DAY)		OT	CA-ROCHE-2573031			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Eye Injury; Fatigue; Headache; Liver Disorder; Therapeutic Product Effect Decreased; Ulcer Haemorrhage	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	20 Mg Was Reduced To 7.5 Mg		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Pantoloc [Pantoprazole]			C				Not Reported
	Humira			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17622228	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217086			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

	Reactine (Cetirizine Hydrochloride)		S	Unknown	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17622407	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217045		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Product Complaint; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Diclofenac			S	Unknown			Actavis
	Diclofenac			S	Unknown			Actavis
	Diclofenac			S	Unknown			Actavis
	Amitriptyline			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Teva
	Celecoxib			S	Unknown			Teva
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Intravenous (not otherwise specified)			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Parenteral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Naproxen			S	Unknown			Teva
	Pregabalin			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Allopurinol			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Amitriptyline Hydrochloride/Perphenazine			S	Unknown			Not Reported
	Apo-Amitriptyline			S	Unknown			Not Reported

Apo-Azathioprine	S	Unknown		Not Reported
Apo-Diclofenac	S	Topical		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Naproxen	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Celebrex	S	Unknown		Not Reported
Celebrex	S	Unknown		Not Reported
Diclofenac Sodium/Misoprostol	S	Unknown		Not Reported
Enbrel	S	Subcutaneous	7.1429 Milligram Daily;	Not Reported
Etanercept	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulphate	S	Unknown		Not Reported
Hydroxychloroquine Sulphate	S	Unknown		Not Reported
Lyrica	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S			Not Reported
Misoprostol	S	Unknown		Not Reported
Naprosyn [Naproxen	S	Unknown		Not Reported
Nifedipine	S	Unknown		Not Reported
Orencia	S	Subcutaneous	107.1429 Milligram Daily;	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Winpred	S	Unknown		Not Reported
Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
Tofacitinib	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17622559	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217497			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depo-Medrol			C	Intra-articular	80 Milligram Daily;		Not Reported
	Humira			C	Subcutaneous			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17622669	EXPEDITED (15-DAY)		OT	CA-SA-2020SA079660			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Leukopenia	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Codeine			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Enbrel			C				Not Reported

	Humira	C	Not Reported
	Orencia	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17622915	DIRECT	Y	HO			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Pancytopenia	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17623040	DIRECT	Y	OT			78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17623288	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05347		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Neutropenia; Platelet Count Decreased; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Etanercept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Advil			C	Unknown	Unknown		Not Reported
	Folic Acid			C	Unknown	Unknown		Not Reported

	Ketorolac	C	Unknown	Unknown		Not Reported
	Methotrexate	C	Unknown			Not Reported
	Naproxen	C	Unknown	Unknown		Not Reported
	Prednisone	C	Unknown	Unknown		Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17623349	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA1578		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Rheumatoid Arthritis	Anakinra			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17623403	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200342132		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Drug Ineffective; Fatigue; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise;	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Swelling; Therapeutic Product Effect Incomplete; Therapy Non-Responder	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17624098	EXPEDITED (15-DAY)		HO, OT	NVSC2020US090011		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Cardiomyopathy; Cardiotoxicity; Dyspnoea Exertional; Orthopnoea; Peripheral Swelling	Hydroxychloroquine			S	Unknown	200 Unk, Bid		Novartis
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17624253	EXPEDITED (15-DAY)		OT	CA-EMD SERONO-E2B_90076287		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Dermatomyositis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Intentional Product Use Issue; Joint Range Of	Metformin Hydrochloride			S	Unknown	Unknown		Not Reported
	Metformin Hydrochloride			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported
	Cymbalta			S	Unknown	Unknown Dosage		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Plaquenil /00072602/			S	Unknown	Unknown		Not Reported

Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Thrombosis; Uterine Disorder; Weight Increased	Prednisone	S	Unknown	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Imuran /00001501/	C	Unknown	Unknown	Not Reported
	Xarelto	C	Unknown	Unknown	Not Reported
	Azathioprine Sodium	C	Unknown		Not Reported
	Methotrexate	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17624589	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-009614			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Methotrexate	S	Oral	Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Subcutaneous	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17625486	EXPEDITED (15-DAY)		HO, LT, OT	MX-ACCORD-178039		29 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Abscess; Endophthalmitis; Liver Abscess; Muscle Abscess; Myositis; Nocardiosis; Off Label Use; Perinephric Abscess; Pneumonia; Pyomyositis	Mycophenolic Acid			S	Oral			Accord
	Hydroxychloroquine			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17625490	EXPEDITED (15-DAY)		OT	FR-SUN		54 YR	Female	FRA

PHARMACEUTICAL INDUSTRIES LTD-2020RR-242736

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Headache; Palpitations	Risedronate			S	Oral	35 Milligram, In Total		Sun
	Plaquenil			S	Oral	1 Dosage Form, Daily		Not Reported
	Cortancyl 20 Mg, Comprime			S	Oral	()		Not Reported
	Pantoprazole			C	Unknown	()		Not Reported
	Izalgi 500 Mg/25 Mg, Gelule			C	Unknown	()		Not Reported
	Levothyrox 75 Microgrammes, Comprime Secable			C	Unknown	()		Not Reported
	Diffu K, Gelule			C	Unknown	()		Not Reported
	Atorvastatine			C	Unknown	()		Not Reported
	Clopidogrel (Chlorhydrate De)			C	Unknown	()		Not Reported
	Procoralan 5 Mg, Comprime Pellicule			C	Unknown	()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2020	16162286	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2733052-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Contraindicated Product Administered; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2020	17625695	EXPEDITED (15-DAY)		DE	IE-ABBVIE-20K-229-3352301-00		57 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Mabthera			S	Unknown			Not Reported
	Plaquenil			S	Subcutaneous			Not Reported
	Seroquel			C				Not Reported
	Arava			C				Not Reported
	Depo-Medrone			C				Not Reported
	Sodium Aurothiomalate			C				Not Reported
	Methotrexate			C				Not Reported
	Protium			C				Not Reported
	Valdoxan			C				Not Reported
	Alendronate			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Prednisolone			C				Not Reported
	Sulfasalazine			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2020	17625752	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217530		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Meloxicam			S	Unknown			Not Reported
	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported

	Arava	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	10991568	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20150323608		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Drug Intolerance; Hypersensitivity; Lip Swelling; Synovitis	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15066519	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2018CA0720		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Kineret			S				Not Reported
	Actemra			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Sulfasalazine	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Apo-Leflunomide	S		Not Reported
	Gold	S	Subcutaneous	Not Reported
	Ilaris	C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15407353	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20180911920		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Contraindicated Product Administered; Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Pain; Pain In Extremity; Pain In Jaw; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

	Methotrexate	S	Oral	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Leflunomide	S	Oral	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15620412	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556731-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre Filled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15625609	EXPEDITED (15-DAY)		DS, HO, OT	CA-ABBVIE-18K-028-2557423-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Apo-Cyclosporine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Ibuprofen			S	Oral			Not Reported
	Infliximab			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Otezla			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Endocervical	Not Reported
Tocilizumab	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Apo-Ibuprofen	S	Oral	Not Reported
Apremilast	S	Unknown	Not Reported
Apremilast	S	Unknown	Not Reported
Apremilast	S		Not Reported
Motrin	S	Oral	Not Reported
Motrin	S	Oral	Not Reported
Leflunomide	S	Oral	Not Reported
Cyclosporine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Ciclosporin	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Ibuprofen	S	Oral	Not Reported
Colchicine	C	Oral	Not Reported
Folic Acid	C		Not Reported
Nitrazepam	C	Oral	Not Reported
Oxycodone	C		Not Reported
Uloric	C		Not Reported
Prednisone	C		Not Reported
Xeljanz	C		Not Reported
Benadryl	C		Not Reported
Dexilant	C	Oral	Not Reported
Febuxostat	C		Not Reported
Gravol	C		Not Reported
Mogadon	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15674250	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573605-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance; Joint Swelling; Polyarthritis; Synovitis; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Mycophenolate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S				Not Reported
	Acetaminophen			C	Oral			Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Actemra			C				Not Reported
	Bisoprolol			C				Not Reported
	Candesartan			C				Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported
	Folic Acid			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Oral			Not Reported
	Sulfamethoxazole/Trimethoprim			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15678194	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2574920-00		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Increased; Colitis; Contraindicated Product Administered; Dental Caries; Diabetes Mellitus	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Diamicron			S	Unknown			Not Reported
	Gliclazide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Disorder; Gastrointestinal Disorder; Haematochezia; Hypertension; Joint Swelling; Musculoskeletal Stiffness; Nausea; Oxygen Saturation Decreased; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Decreased; Weight Increased	Orencia	S	Unknown		Not Reported
	Rituxan	S	Intravenous drip		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Asacol	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	225.0	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Norvasc	S	Oral		Not Reported
	Norvasc	S	Oral		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Acetaminophen	C	Oral		Not Reported
	Aerius	C			Not Reported
	Crestor	C			Not Reported
	Diphenhydramine	C	Oral		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)		Not Reported
	Amlodipine Besilate	C	Unknown		Not Reported
	Atacand Plus	C			Not Reported
	Bisoprolol Fumarate	C			Not Reported
	Depo-Medrol	C	Intra-articular		Not Reported
	Ferrous Gluconate	C			Not Reported
	Folic Acid	C			Not Reported
	Tylenol	C			Not Reported
	Vitamin D3	C			Not Reported
	Rosuvastatin Calcium	C			Not Reported
	Ebastine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15702726	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2580931-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Contraindicated Product Administered; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Celebrex			C				Not Reported
	Lyrica			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15707673	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2584580-00		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Drug Ineffective; Fall; Off Label Use; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

				otherwise specified)	
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15733752	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594187-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Apo-Minocyclin			S	Unknown			Not Reported
	Apo-Minocyclin			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			C	Unknown			Not Reported

	Hydroxychloroquine Sulfate	C			Not Reported
	Xeljanz	C	Unknown		Not Reported
	Hydroxychloroquine	C	Ophthalmic		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15734078	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594192-00		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15734387	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594151-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Contraindicated Product Administered; Drug Intolerance; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

							otherwise specified)			
						Simponi	S	Subcutaneous		Not Reported
						Xeljanz	C	Oral		Not Reported
						Prednisone	C	Oral		Not Reported
						Lyrica	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15739251	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594156-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Varilrix			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported
	Cortisone Acetate			C	Subcutaneous			Not Reported

	Desoximetasone	C	Oral	Not Reported
	Desoximetasone	C	Subcutaneous	Not Reported
	Diclofenac	C	Subcutaneous	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15930738	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2655654-00		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cataract; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Metformin Hydrochloride			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported
	Topicort			S	Unknown			Not Reported
	Glumetza			S	Unknown			Not Reported
	Altace			C	Unknown			Not Reported
	Asa			C				Not Reported
	D-Alpha Tocopherol			C				Not Reported
	Folic Acid			C	Unknown	1.0		Not Reported
	Methotrexate			C	Oral			Not Reported
	Rosuvastatin Calcium			C				Not Reported
	Rosuvastatin Calcium			C				Not Reported
	Vitamin D			C	Unknown			Not Reported
	Docosahexaenoic Acid			C				Not Reported
	Eicosapentaenoic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16040473	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1020190			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Pain; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Meloxicam			S	Unknown			Teva
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16301153	EXPEDITED (15-DAY)		OT	CA-SA-2019SA121523			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Lyrica			C	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16381114	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2804954-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Rash; Rheumatoid Arthritis; Unevaluable Event; Urticaria	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Amlodipine			C				Not Reported
	Arava			C				Not Reported
	Benadryl			C				Not Reported
	Naproxen			C				Not Reported
	Prednisone			C				Not Reported
	Tofacitinib Citrate			C				Not Reported
	Viread			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16441274	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2822469-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Contraindicated Product Administered; Drug Intolerance; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Lyrica	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16443280	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2819775-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Prednisone		C	Intravenous (not otherwise specified)	Not Reported
	Xeljanz		C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16497972	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019026465			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Off Label Use; Rheumatoid Arthritis; Somnolence; Visual Impairment	Cimzia			S	Subcutaneous			Not Reported
	Acetaminophen			S	Endocervical			Not Reported
	Actemra			S				Not Reported
	Arava			S		20 Milligram, Once Daily (Qd)		Not Reported
	Arava			S		10 Milligram, Once Daily (Qd)		Not Reported
	Enbrel			S		50 Milligram, Weekly (Qw)		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulphate			S		200 Milligram, 2x/Day (Bid)		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	500 Milligram, 2x/Day (Bid)		Not Reported
	Sulfasalazine			S	Oral	2000 Milligram, 2x/Day (Bid)		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram, 2x/Day (Bid)		Not Reported
	Methotrexate			C		Unk, Weekly (Qw)		Not Reported

	Meloxicam	C				Not Reported
	Synthroid	C				Not Reported
	Acetaminophen And Codeine Phosphate	C				Not Reported
	Apo-Prednisone	S	Oral	20 Nanogram		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S		200 Milligram, 2x/Day (Bid)		Not Reported
	Codeine	C				Not Reported
	Tylenol [Paracetamol]	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16714535	EXPEDITED (15-DAY)		OT	CA-SA-2019SA216686			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported
	Simponi			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Celebrex			C				Not Reported
	Lyrica			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16717736	EXPEDITED (15-DAY)		OT	CA-SA-2019SA216698		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Metals; Arthralgia; Cerebral Disorder; Condition Aggravated; Cystitis;	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Ibuprofen			S	Oral	400 Mg 3-4/Day		Not Reported
	Methotrexate			S		25 Mg, Qw		Not Reported

Disturbance In Attention; Drug Intolerance; Gait Disturbance; Grip Strength Decreased; Hypersensitivity; Intentional Product Use Issue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Stiffness; Pneumonitis; Therapeutic Product Effect Incomplete	Hydroxychloroquine		S			Sanofi
	Gold		S	Intramuscular	10 Mg, 1x	Not Reported
	Xeljanz		C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17156996	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191212448			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Reactine (Cetirizine Hydrochloride)			S	Unknown			Johnson And Johnson
	Reactine (Cetirizine Hydrochloride)			S	Unknown			Johnson And Johnson
	Cetirizine Hydrochloride			S	Unknown			Johnson And Johnson
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Johnson And Johnson
	Pseudoephedrine Hydrochloride			S	Unknown			Johnson And Johnson
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Janssen
	Actemra			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported

Enbrel	S	Subcutaneous		Not Reported
Folic Acid	S	Unknown		Not Reported
Folic Acid	S	Unknown		Not Reported
Fosamax	S	Oral		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Intra-arterial		Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil /00072602/	S	Unknown		Not Reported
Prednisone	S	Oral		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
Sulfasalazine	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous		Janssen
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17173636	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053782			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand	Cimzia			S	Subcutaneous			Ucb
	Cetirizine Hydrochloride			S		Unk		Ucb
	Cetirizine Hydrochloride			S				Ucb
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported

Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride	S			Not Reported
	Pseudoephedrine Hydrochloride	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Tocilizumab	S	Subcutaneous		Not Reported
	Apo-Prednisone	S			Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Desoximetasone	S	Oral		Not Reported
	Diclofenac Sodium	S			Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Folic Acid	S		1 Milligram	Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Folic Acid	S		1 Milligram	Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram Solution	Ucb
	Hydroxychloroquine	S			Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Methotrexate	S	Oral	Solution	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram Solution	Not Reported
	Methotrexate Sodium	S			Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S		Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S			Not Reported

	Prednisone	S	Oral		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Subcutaneous	500 Milligram	Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17200098	EXPEDITED (15-DAY)		OT	SE-ADVANZ PHARMA-201912003018			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Lupus Erythematosus; Drug Ineffective	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	200 Mg, Bid ,1 Tablet Twice A Day For 2 Weeks		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	1 Dosage Form		Concordia
	Trombyl			C		75 Mg		Not Reported
	Candesartan			C		16 Mg		Not Reported
	Levaxin			C		25 Mg		Not Reported
	Methotrexate			C		Unk		Not Reported
	Dermovate			C		Unk		Not Reported
	Omeprazol			C		Unk		Not Reported
	Rosuvastatin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17350398	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020003181			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Joint Swelling; Rheumatoid Arthritis; Synovitis; X-Ray Abnormal	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	200 Milligram		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Enbrel			S		50 Milligram		Not Reported

	Enbrel	S		50 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	S		Unk	Not Reported
	Methotrexate	S		25 Milligram, Weekly (Qw)	Not Reported
	Leflunomide	S			Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Sulfasalazine	S		1 Gram, 2x/Day (Bid)	Not Reported
	Hydroxychloroquine Sulfate	S		400 Milligram, Once Daily (Qd)	Not Reported
	Xeljanz	C		5 Milligram, 2x/Day (Bid)	Not Reported
	Xeljanz	C		11 Milligram, Once Daily (Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17391221	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170826218		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Distension; Abdominal Distension; Adverse Reaction; Arthralgia; Coeliac Disease; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury; Dyspepsia; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Insomnia; Joint Swelling; Loss Of Personal	Stelara			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Sirukumab			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nail Disorder; Nausea; Off Label Use; Onychomycosis; Pain; Product Use In Unapproved Indication; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sleep Disorder; Treatment Failure	Xeljanz	S	Oral	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Otezla	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Salazopyrin	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Tocilizumab	S		Not Reported
	Orencia	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Apo Prednison	S	Oral	Not Reported
	Rheumatrex	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17563093	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20170105863			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adjustment Disorder With Depressed Mood; Alopecia; Amnesia; Contraindicated Product	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Humira			S	Subcutaneous			Not Reported

Administered; Delirium; Diabetes Mellitus; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Gait Disturbance; Glossodynia; Grip Strength Decreased; Hip Arthroplasty; Infection; Knee Arthroplasty; Maternal Exposure During Pregnancy; Mobility Decreased; Muscular Weakness; No Adverse Event; Pain; Pain In Extremity; Pemphigus; Peripheral Swelling; Product Use Issue; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Fusion Surgery; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Walking Aid User; Weight Decreased; Wound Infection	Humira	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Cosentyx	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride W/Tri/00005601/	S	Unknown	Not Reported
	Reactine /00884302/	S	Unknown	Not Reported
	Naprosyn /00256201/	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17628438	EXPEDITED (15-DAY)		HO	FR-ADVANZ PHARMA-202003002241			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Fibromyalgia; Malaise; Pleural Effusion	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	1 Dosage Form, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	2 Dosage Form,Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17628439	EXPEDITED (15-DAY)		OT	BR-ADVANZ PHARMA-202003002041			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence	Hydroxychloroquine			S	Unknown	Unk, (Coated Tablets)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17628622	EXPEDITED (15-DAY)		DS, OT	FR-ADVANZ PHARMA-202003002294			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiovascular Disorder; Chronic Obstructive Pulmonary Disease; Diabetes Mellitus; Infection; Pneumonia; Respiratory Distress; Wheelchair User	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk (Film-Coated Tablet)		Concordia
	Cortancyl			C		Unk		Not Reported
	Vitamin D [Vitamin D Nos]			C		Unk		Not Reported
	Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17628632	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3352546-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Rheumatoid Arthritis	Humira	S	Subcutaneous	Not Reported
	Codeine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17628737	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009312			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Rheumatoid Arthritis	Leflunomide			S	Oral	Unk		Apotex
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Simponi			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17628958	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020014088		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Oral Pain; Oropharyngeal Pain; Stomatitis	Cimzia			S	Subcutaneous	200 Milligram, Ev 2 Weeks(Qow)		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, 2x/Day (Bid)		Not Reported
	Methotrexate			S	Subcutaneous	200 Milligram		Not Reported
	Benzylhydrochlorothiazide			C				Not Reported
	Coumadin			C				Not Reported
	Cyanocobalamin			C				Not Reported

Eltroxin	C		Not Reported
Metoprolol	C		Not Reported
Pravachol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629123	EXPEDITED (15-DAY)		HO, OT	CA-UCBSA-2020014089			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Etanercept			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Tocilizumab			S		160 Milligram		Not Reported
	Azathioprine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629213	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202003002163			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Condition Aggravated; Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629297	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217561			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Meloxicam	S	Unknown	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Barr
	Prednisone	S	Unknown	Actavis
	Actemra	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629303	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217500		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung;	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Oral			Not Reported

Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629306	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217468			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate			S	Unknown			Barr
	Diclofenac Sodium			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629352	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217523			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depo-Medrol			C	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629366	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217536			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength	Meloxicam			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported

Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Sulfasalazine	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629396	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217963		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629398	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1218003			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Subcutaneous			Barr

Fatty Liver Disease; Pruritus; Treatment Failure	Azathioprine	S	Unknown		Not Reported
	Leflunomide	S	Oral		Barr
	Actemra	S	Subcutaneous	23.1429 Milligram Daily;	Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
	Kevzara	S	Subcutaneous		Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Esomeprazole	C	Unknown		Not Reported
	Magnesium	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629497	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202003001847			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Height Decreased; Drug Tolerance Increased; Hypoacusis; Joint Injury; Joint Swelling; Migraine; Musculoskeletal Disorder; Therapeutic Product Effect Decreased; Vomiting	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid, One In The Morning One In Night		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629815	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202003002043			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Exposure During Pregnancy; Gestational Diabetes; Shortened Cervix	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil		S	Oral	200 Mg	Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17630225	EXPEDITED (15-DAY)		OT	NVSC2020CA090993			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Transaminases Increased	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	10 Mg, Unknown		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unknown		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17631124	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3352969-00		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hyperbilirubinaemia; Hypocoagulable State	Kaletra			S	Oral			Not Reported
	Hidroxicloroquina			S	Oral	200 Mg/12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17631943	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217985		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Leflunomide			S	Unknown			Barr

	Methotrexate	S	Oral		Not Reported
	Methotrexate	S			Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
	Neoral	S	Subcutaneous		Not Reported
	Neoral	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632010	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318931			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Nausea; Off Label Use; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Treatment Failure; Urticaria	Simponi			S	Subcutaneous			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Orencia			S	Subcutaneous			Not Reported

	Plaquenil /00072602/	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Mefenamic Acid	S	Oral	Not Reported
	Gold	S	Unknown	Not Reported
	Arthrotec	C	Oral	Not Reported
	Tylenol /00020001/	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632057	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217417			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Alendronate Sodium			S	Oral			Actavis
	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Intra-arterial	25 Mg		Barr
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Oral			Actavis
	Prednisone			S	Unknown			Actavis
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cortisone Acetate			S	Topical			Not Reported

Desoximetasone	S	Oral		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Folic Acid	S	Unknown		Not Reported
Folic Acid	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Subcutaneous		Not Reported
Plaquenil	S	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632099	NON-EXPEDITED		OT	NVSC2020US092034		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Diastolic Dysfunction	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632120	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217560			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Meloxicam			S	Oral	7.5 Mg		Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S		20 Millimol Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Methotrexate	S	Oral		Not Reported
	Sulfasalazine	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632164	EXPEDITED (15-DAY)		OT	NVSC2020FR079225		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acarodermatitis; Ocular Toxicity	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Belimumab			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632212	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020014049		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Apo-Azathioprine			S				Not Reported
	Arava			S		Unk		Not Reported
	Azathioprine			S				Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Cephalexin Monohydrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632213	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020014044		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Cataract; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Eye Disorder; Glaucoma; Hernia; Herpes Zoster; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Off Label Use; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S				Not Reported
	Enbrel			S	Subcutaneous	1 Dosage Form, Weekly (Qw)		Not Reported
	Glumetza			S		500 Milligram, 2x/Day (Bid)		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S				Not Reported
	Xeljanz			S	Oral	5 Milligram, 2x/Day (Bid)		Not Reported
	Acetaminophen			C				Not Reported
	Altace			C				Not Reported
	Arava			C				Not Reported
	Asa			C				Not Reported
	Codeine			C				Not Reported
	D-Alpha Tocopherol			C				Not Reported
	Ergocalciferol			C				Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C	Oral			Not Reported

	Rosuvastatin Calcium			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632322	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217430			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632341	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217513			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling;	Meloxicam			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Humira		S	Subcutaneous		Not Reported
	Methotrexate		S	Oral		Not Reported
	Arava		S	Unknown	20 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate		S	Oral		Not Reported
	Sulfasalazine		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632490	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-2014318US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Epistaxis; Headache; Insomnia; Nausea; Osteonecrosis Of Jaw; Transaminases Increased	Risedronate Sodium Unk			S	Oral	35 Mg, Q Week		Allergan
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Mycophenolate Mofetil			S	Oral	500 Mg, Bid		Not Reported
	Mycophenolate Mofetil			S	Oral	1 G, Bid		Not Reported
	Plaquenil			S	Unknown	300 Mg, Qd		Not Reported
	Azathioprine			C	Oral	50 Mg, Qd		Not Reported
	Azathioprine			C	Oral	150 Mg, Qd		Not Reported
	Azathioprine			C	Oral	100 Mg, Bid		Not Reported
	Humira			C	Subcutaneous	40 Mg, Q2weeks		Not Reported
	Ketoprofen			C	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Q Week		Not Reported
	Prolia			C	Subcutaneous	Actual: 60 Mg, Every 6 Months		Not Reported
	Rituximab			C	Intravenous (not otherwise specified)	1 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632612	EXPEDITED (15-DAY)		OT	CA-SA-2020SA073892			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Drug Ineffective; Hepatic Fibrosis; Therapeutic Response Decreased	Leflunomide	S		Sanofi
	Hydroxychloroquine	S		Sanofi
	Methotrexate	S		Not Reported
	Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632859	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217558			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Meloxicam			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral	2.8571 Milligram Daily;		Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17633310	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217525		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown	22.8571 Milligram Daily;		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Depo-Medrol	C	Other	Not Reported
	Diclofenac	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17633436	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217998			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Tylenol Arthritis Pain 8h			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17633463	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217508			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Meloxicam			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			S	Unknown	200 Milligram Daily;		Not Reported
	Actemra			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17633465	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217531			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain;	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Depo-Medrol			C				Not Reported
	Diclofenac			C				Not Reported
	Humira			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	14299100	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2017050873			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Contraindicated Product Administered; Drug Ineffective; Foot Deformity; Loss Of Consciousness; Mobility Decreased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Anakinra			S		Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Gold			S		Unk		Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	15624086	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557445-00		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	15679987	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2573622-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fatigue; Joint	Humira			S	Subcutaneous			Not Reported

Arthroplasty; Rheumatoid Arthritis; Weight Increased; Wheelchair User	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Indometacin	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Morphine Sulfate	S	Unknown	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Statex (Morphine Sulfate)	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Acetaminophen	C		Not Reported
	Prednisone	C	Unknown	Not Reported
	Statex	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	15711682	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587778-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Other	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Parenteral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Imuran	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	16182582	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2738227-00		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Off Label Use; Pain; Product Use Issue; Rheumatoid Arthritis; Sciatica	Humira			S	Subcutaneous			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Levothyroxine			S	Subcutaneous			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Ramipril			S	Unknown			Not Reported

Codeine	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Apo-Ramipril	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Codeine Phosphate	S	Unknown	Not Reported
Cosopt	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Levothyroxine Sodium	S	Unknown	Not Reported
Altace	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Acetaminophen	S	Unknown	Not Reported
Acetaminophen W/Codeine Phosphate	C	Intravenous (not otherwise specified)	Not Reported
Tylenol No.2	C	Unknown	Not Reported
Acetaminophen W/Caffeine	C	Unknown	Not Reported
Plaquenil	C		Not Reported
Acetaminophen/Caffeine/Codeine Phosphate	C		Not Reported
Caffeine W/Dihydrocodeine Bitartrate/Paraceta	C		Not Reported
Caffeine	C		Not Reported
Dorzolamide Hydrochloride/Timololmaleate	C	Ophthalmic	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	16805717	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2921109-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy	Humira			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Otezla			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			C				Not Reported
	Methotrexate			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17257461	EXPEDITED (15-DAY)		DS, HO, OT	NVSC2020AU004219			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Ageusia; Arthralgia; Depression; Dna Antibody Negative; Drug Interaction; Fibromyalgia; Gait Disturbance; Liver Function Test Abnormal; Migraine; Nausea; Panic	Mycophenolate Mofetil			S	Oral	500 Mg, Tid		Novartis
	Mycophenolate Mofetil			S				Novartis
	Methotrexate			S	Subcutaneous	10 Mg, Biw		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Biw		Not Reported
	Methotrexate			S	Subcutaneous	10 Unk, Biw (Mcg)		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported

Attack; Paraesthesia; Psoriasis; Psoriatic Arthropathy; Respiratory Syncytial Virus Infection; Sleep Disorder; Suicidal Ideation; Systemic Lupus Erythematosus; Tachyarrhythmia; Type 1 Diabetes Mellitus; Urinary Tract Infection; Viral Tonsillitis	Rosuvastatin	S	Unknown	10 Mg	Not Reported
	Ezetimibe	S	Unknown	10 Mg	Not Reported
	Ramipril	S	Unknown	Unk Mg, Unknown (5-10)	Not Reported
	Topiramate	S	Unknown	200 Mg, Unknown	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Paracetamol	S	Unknown	Unk	Not Reported
	5-Methyltetrahydrofolate	S	Unknown	Unk	Not Reported
	Oxycontin	S	Oral	10 Mg, Bid	Not Reported
	Endone	S	Oral	5 Mg, Qd	Not Reported
	Aspirin	S	Unknown	100 Mg, Unknown	Not Reported
	Prasugrel	S	Unknown	10 Mg, Qd	Not Reported
	Ivabradine	S	Unknown	7.5 Mg, Bid	Not Reported
	Sildenafil	S	Oral	12.5 Mg, Prn	Not Reported
	Gtn	S	Oral	Unk	Not Reported
	Cannabis Sativa Oil	S	Unknown	Unk	Not Reported
	Reboxetine	S	Unknown	4 Mg, Bid	Not Reported
	Cholecalciferol	S	Unknown	50 Unk, Qd (Mcg)	Not Reported
	Novorapid	S	Subcutaneous	Unk (Pump With Continuous Bgl Monitor)	Not Reported
	Glucagen Hypokit	S	Unknown	Unk	Not Reported
	Mirena	S	Unknown	52 Mg, Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Biw	Not Reported
	Prednisolone	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17374357	NON-EXPEDITED			US-PFIZER INC-2020048790		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Enbrel	S	Unk		Pfizer
	Methotrexate Sodium	S	Unk		Pfizer
	Humira	S	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17394735	EXPEDITED (15-DAY)		OT	RU-ADVANZ PHARMA-202002000642			Unknown	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd (Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	2 Dosage Form, Qd (Tablet) (Increased The Dose)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17557550	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318948		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Fibromyalgia; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Simponi			S	Subcutaneous			Janssen
	Plaquenil /00072602/			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17557559	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318949			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Arava			S	Unknown			Not Reported
	Azithromycin			S	Unknown	Pms		Not Reported
	Benadryl /00000402/			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Demerol			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran /00001501/			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Procytox			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib Citrate			S	Oral			Not Reported
	Ezetrol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17557586	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318928		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Simponi			S	Subcutaneous			Janssen
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17558039	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20200318940			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Muscle Spasms; Off Label Use; Rheumatoid Arthritis	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Plaquenil /00072602/			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Oxycodone Terephthalate			C	Unknown			Not Reported
	Percocet /00446701/			C	Unknown			Not Reported
	Thiamine Hydrochloride			C	Unknown			Not Reported
	Acetaminophen W/Oxycodone Hydrochloride			C	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Oxycodone Terephthalate			C	Unknown			Not Reported
	Acetaminophen W/Oxycodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17566305	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200320978			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Infection; Joint Swelling; Lower Respiratory Tract Infection; Nausea;	Simponi			S	Subcutaneous			Janssen
	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen

Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Remicade	S	Intravenous (not otherwise specified)		Janssen
	Rituxan	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	Duration- 730 And 731 (Unspecified Units)	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Diclofenac Sodium And Misoprostol	S	Unknown		Not Reported
	Diclofenac Sodium And Misoprostol	S	Unknown		Not Reported
	Diclofenac Sodium And Misoprostol	S	Unknown		Not Reported
	Cimzia	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported

	Leflunomide	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Vitamin D3	C	Unknown	Not Reported
	Imuran /00001501/	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported
	Arthrotec	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17566309	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200320884		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Carpal Tunnel Syndrome; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Knee Arthroplasty; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil /00072602/			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17575971	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2020AP008932		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Q.O.Wk.		Not Reported
	Gold			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Cyclical		Not Reported
	Orencia			S	Subcutaneous	250 Mg, Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	25 Unk, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Unk (1 Every 6 Weeks)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Unk, Cyclical		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Salazopyrin	S	Unknown	Unk	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
Celebrex	C	Unknown	Unk	Not Reported
Actemra	C	Unknown	Unk	Not Reported
Arava	C	Oral	10 Mg, Unk	Not Reported
Bifidobacterium Bifidum	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Methotrexate	C	Subcutaneous	15 Mg, Q.Wk.	Not Reported
Methotrexate	C	Unknown	20 Mg, Q.Wk.	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	40 Mg, Unk	Not Reported
Prednisone	C	Unknown	250 Mg, Unk	Not Reported
Simponi	C	Unknown	Unk	Not Reported
Sulfasalazine	C	Unknown	Unk	Not Reported
Wellbutrin	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Mg, Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17577750	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200320438		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S				Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Lyrica	C		Not Reported
	Prednisone	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17596897	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068369		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Leflunomide			S		Unk		Sanofi
	Leflunomide			S		Unk		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil			S		Unk		Sanofi
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17596961	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068453			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Arava	S		Unk	Sanofi
	Prednisone	S		Unk	Not Reported
	Cetirizine Hydrochloride	S		10 Mg	Not Reported
	Cetirizine Hydrochloride	S		10 Mg	Not Reported
	Cortisone Acetate	S		Unk	Not Reported
	Folic Acid	S		5 Mg	Not Reported
	Alendronate Sodium	S		Unk	Not Reported
	Hydroxychloroquine	S		Unk	Sanofi
	Methotrexate	S		Unk	Not Reported
	Plaquenil	S		Unk	Sanofi
	Pseudoephedrine Hydrochloride	S		Unk	Sanofi
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S		Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S		Unk	Not Reported
	Actemra	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17597473	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068824		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Rheumatoid Arthritis; Shoulder Operation;	Leflunomide			S				Sanofi
	Leflunomide			S		Unk		Sanofi
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

Therapeutic Response Decreased	Methotrexate	S			Not Reported
	Orencia	S			Not Reported
	Sulfasalazine	S			Not Reported
	Cymbalta	C			Not Reported
	Hydromorphone	C			Not Reported
	Hydromorph Contin	C			Not Reported
	Lyrica	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17597488	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068873		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Leflunomide			S	Oral	5 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	5 Mg		Sanofi
	Methotrexate			S	Unknown	5 Mg		Not Reported
	Cimzia			S	Subcutaneous	200 Mg		Not Reported
	Enbrel			S	Unknown	50 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Unknown	750 Mg		Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17608427	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009050			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hepatitis; Hypersensitivity;	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Endocervical	Unk		Apotex
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

Inflammatory Marker Increased; Keratitis; Off Label Use; Skin Reaction; Synovitis; Thyroid Cancer	Enbrel	S	Unknown	50 Mg, Unk	Not Reported
	Etanercept	S	Unknown	50 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Aspirin /00002701/	C	Unknown	Unk	Not Reported
	Avapro	C	Unknown	Unk	Not Reported
	Biaxin	C	Unknown	Unk	Not Reported
	Humalog	C	Unknown	Unk	Not Reported
	Insulin	C	Oral	Unk	Not Reported
	Lantus	C	Unknown	Unk	Not Reported
	Metformin Hydrochloride	C	Unknown	Unk	Not Reported
	Nystatin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17608759	EXPEDITED (15-DAY)		OT	IT-ADVANZ PHARMA-202002001099			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Platelet Count Decreased; Red Blood Cell Count Decreased; Visual Impairment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Imiquimod			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17635250	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020014082		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S				Not Reported

Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S			Not Reported
	Hydroxychloroquine Sulfate		S			Not Reported
	Leflunomide		S			Not Reported
	Methotrexate		S		25 Milligram, Once Daily (Qd)	Not Reported
	Orencia		S			Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution For Intravenous	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17635999	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1218958			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17636247	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-PBT-000018			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Contraindicated Product Administered; Death; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Product Monitoring Error; Truncus Arteriosus Persistent; Ventricular Septal Defect	Tacrolimus			S	Transplacental			Panacea Biotec
	Hydroxychloroquine			S	Transplacental			Not Reported
	Ramipril			S	Transplacental			Not Reported
	Ramipril			S	Transplacental			Not Reported
	Simvastatin			S	Transplacental			Not Reported
	Pantoprazole			S	Transplacental			Not Reported
	Metamizole Sodium			S	Transplacental			Not Reported
	Nicotine			S	Transplacental			Not Reported
	Aliskiren			S	Transplacental			Not Reported
	Aliskiren			S	Transplacental			Not Reported
	Torasemide			S	Transplacental			Not Reported
	Salbutamol Sulfate			S	Unknown			Not Reported
	Xarelto			S	Transplacental			Not Reported
	Ezetimibe			S	Transplacental			Not Reported
	Prednisolone			S	Transplacental			Not Reported
	Dalteparin Sodium			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Transplacental			Not Reported
	Acetylsalicylic Acid			S	Transplacental			Not Reported
	Acetylsalicylic Acid			S	Transplacental			Not Reported
	Novaminsulfon			S	Transplacental			Not Reported
	Novaminsulfon			S	Transplacental			Not Reported
	Torasemide			S	Transplacental			Not Reported
	Rituximab			S	Transplacental			Not Reported
	Enoxaparin Sodium			S	Transplacental			Not Reported
	Misoprostol			C	Transplacental			Not Reported

	Ramipril	S	Transplacental	Not Reported
	Enoxaparin Sodium	C	Transplacental	Not Reported
	Advagraf	S	Transplacental	Not Reported
	Advagraf	S	Transplacental	Not Reported
	Advagraf	S	Transplacental	Not Reported
	Mifegyne	C	Transplacental	Not Reported
	Cyclophosphamide	C	Transplacental	Not Reported
	Heparin	S	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17636295	EXPEDITED (15-DAY)		LT	NVSC2020US090949			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Near Death Experience	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis
	Benadryl			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17636540	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1219972		54 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Hidroxicloroquina (2143a)			S	Oral	20 Mg		Teva
	Hidroxicloroquina (2143a)			S	Oral	400mg/12h Dia 1 Seguido De 200mg/12h		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17636766	EXPEDITED (15-DAY)		OT	CA-SA-2020SA085603			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus	Topicort			S	Topical			Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S				Sanofi

Erythematosus	Methotrexate	S				Not Reported
	Folic Acid	S	Subcutaneous	1 Mg		Not Reported
	Prednisone	S				Not Reported
	Alendronate Sodium	S				Not Reported
	Cetirizine Hydrochloride	S				Not Reported
	Actemra	S				Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Enbrel	S				Not Reported
	Humira	S	Subcutaneous			Not Reported
	Orencia	S				Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17637797	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029039		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Jaw; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Azathioprine			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17637833	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1219073		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Ciclosporin	S	Unknown			Ivax
	Azathioprine	S	Unknown			Not Reported
	Azathioprine	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Barr
	Methotrexate	S	Unknown			Barr
	Mycophenolate Mofetil	S	Unknown			Teva
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17638187	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1219970		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mixed Liver Injury	Hidroxicloroquina (2143a)			S	Oral	400mg / 12h Day 1 Followed By 200mg / 12h		Teva
	Hidroxicloroquina (2143a)			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17638596	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS-2020GMK047124			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased;	Gabapentin			S	Unknown	100 Milligram, Bid		Glenmark
	Actemra			S	Intravenous (not	488 Milligram; 1 Every 1		Not Reported

Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure			otherwise specified)	Month	
	Arava	S	Intravenous (not otherwise specified)	20 Milligram, Qd	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	2.5 Gram, Qd	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, 1 Every 3 Week	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram; 1 Every 3 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Qw (1 Every 1 Week)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Enbrel	S	Unknown	50 Milligram, Qw (1 Every 1 Week)	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, 1 Every 1 Month	Not Reported
	Ascorbic Acid	C	Unknown	Unk	Not Reported
	Biotin	C	Unknown	Unk	Not Reported
	D-Alpha Tocopherol	C	Unknown	1200 Milligram, Bid (2 Every 1 Day)	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram, Qd	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	Unk, Od	Not Reported
	Ergocalciferol	C	Unknown	Unk, Od (1 Every 1 Day)	Not Reported
	Ergocalciferol	C	Unknown	400 Iu International Unit(S), Qd	Not Reported
	Esomeprazole	C	Unknown	40 Milligram, Bid (2 Every 1 Day)	Not Reported
	Ferrous Fumarate	C	Unknown	300 Milligram, Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Hydroxocobalamin	C	Unknown	Unk	Not Reported

Loperamide Hydrochloride	C	Unknown	2.5 Milligram, Unk	Not Reported
Nasonex	C	Unknown	2 Dosage Form, Bid	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Nortriptyline Hydrochloride	C	Oral	40 Milligram, Od	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Milligram, Unk	Not Reported
Prednisone	C	Unknown	5.0 Gigabecquerel, Od	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Risedronate Sodium	C	Unknown	36 Milligram, Qw (1 Every 1 Week)	Not Reported
Sodium Ascorbate	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Od	Not Reported
Tylenol /00020001/	C	Unknown	1000 Milligram, Qd	Not Reported
Vitamin A /00056001/	C	Unknown	Unk	Not Reported
Vitamin C /00008001/	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17638618	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1219130			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia Single-Use Prefilled			S	Subcutaneous			Not Reported

	Syringe									
	Enbrel			S	Unknown					Not Reported
	Humira			S	Subcutaneous					Not Reported
	Hydroxychloroquine Sulfate			S	Unknown					Not Reported
	Remicade			S	Intravenous (not otherwise specified)					Not Reported
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17638636	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1219180		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17638655	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1218933		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Ciclosporin	S	Unknown	Ivax
	Azathioprine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Barr
	Mycophenolate Mofetil	S	Unknown	Teva
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17638683	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1218942		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Overlap Syndrome; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Ciclosporin			S	Unknown			Ivax
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17639284	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003002713			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Hepatic Fibrosis; Therapeutic Response Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17639471	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC-2020-FR-001059			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Cardiomyopathy; Cutaneous Lupus Erythematosus; Neutropenia; Renal Failure; Retinal Injury; Thrombocytopenia; Toxicity To Various Agents	Chloroquine Phosphate			S	Unknown	300 Milligram, Qd		Ipca
	Hydroxychloroquine			S	Unknown	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17641570	EXPEDITED (15-DAY)		OT	NVSC2020US094182		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17641778	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS			Female	CAN

SQUIBB COMPANY-
BMS-2020-028981

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Piroxicam			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	12736125	NON-EXPEDITED			US-PFIZER INC-2016421350		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Animal Scratch; Impaired Healing; Therapeutic Product Effect Incomplete	Xeljanz			S		5 Mg, Unk		Pfizer
	Xeljanz			S		10 Mg, Unk		Pfizer

	Xeljanz	S	5 Mg, Unk	Pfizer
	Hydroxychloroquine	S	200 Mg, Unk	Not Reported
	Duloxetine	S	30 Mg, Unk	Not Reported
	Vitamin D2	S	50000 Iu, Weekly	Not Reported
	Alendronate	S	70 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	13519393	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038017		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Synovitis; Treatment Failure	Orencia			S	Unknown	750 Mg		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Oral	20 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	20 Milligram		Not Reported
	Sodium Aurothiomalate			S	Parenteral	50 Milligram		Not Reported
	Leflunomide			S	Oral	20 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	13676502	EXPEDITED (15-DAY)		OT	CA-TEVA-780631ACC		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Actonel			S	Unknown			Teva
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate Sodium			S	Subcutaneous			Barr
	Methotrexate Sodium			S	Subcutaneous			Barr
	Risedronic Sodium			S	Unknown			Teva
	Risedronic Sodium			S	Oral			Teva
	Risedronic Sodium			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown	300 Milligram Daily;		Not Reported
	Plaquenil			S	Oral	300 Milligram Daily;		Not Reported
	Plaquenil			S	Oral	300 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	1 Dosage Forms Daily;	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram Daily;	Not Reported
	Apo-Risedronate	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	15621982	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557440-00		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	15623808	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555897-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Unevaluable Event	Humira			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Minocycline			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

	Amoxicillin Sodium And Clavulanate Potassium	C	Unknown	Not Reported
	Amoxil	C	Unknown	Not Reported
	Clavulin	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported
	Bcg	C	Intravesical	Not Reported
	Bcg	C	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Amoxicillin Trihydrate And Clavulanate Potass	C		Not Reported
	Risedronate	C	Oral	Not Reported
	Amoxicillin And Clavulanate Potassium	C	Unknown	Not Reported
	Adalimumab	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	15630623	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556317-00		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; No Adverse Event; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Rituximab	S	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	15651514	EXPEDITED (15-DAY)		DS, LT, OT	CA-GLAXOSMITHKLINE-CA2015187246			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus	Cetirizine Hydrochloride			S		10 Mg, Unk		Glaxosmithkline
	Cetirizine Hydrochloride			S		Unk		Glaxosmithkline
	Cetirizine Hydrochloride			S	Oral	10 Milligram, Once Daily (Qd)		Glaxosmithkline
	Cetirizine Hydrochloride			S	Oral	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S		Unk		Glaxosmithkline
	Zyrtec-D			S		10 Mg, Unk		Glaxosmithkline
	Zyrtec-D			S				Glaxosmithkline
	Cirrus			S		Unk		Glaxosmithkline
	Cetirizine Hydrochloride			S	Oral	10 Milligram, Once Daily (Qd)		Glaxosmithkline
	Cetirizine Hydrochloride			S				Glaxosmithkline
	Folic Acid			S		5 Mg, Unk		Glaxosmithkline
	Folic Acid			S		5 Milligram		Glaxosmithkline
	Folic Acid			S		1 Milligram		Glaxosmithkline
	Folic Acid			S		1 Mg		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Pseudoephedrine Hydrochloride			S		Unk		Glaxosmithkline
	Pseudoephedrine Hydrochloride			S		1 Milligram		Glaxosmithkline
	Pseudoephedrine Hydrochloride			S		25 Milligram		Glaxosmithkline

Erythematosus; Treatment Failure; Wound	Pseudoephedrine Hydrochloride	S		10 Milligram	Glaxosmithkline
	Diclofenac Sodium	S		Unk	Glaxosmithkline
	Paracetamol	S		Unk	Glaxosmithkline
	Cortisone Acetate	S	Topical	25 Milligram	Glaxosmithkline
	Diclofenac	S		Unk	Glaxosmithkline
	Topicort	S	Cutaneous	Unk	Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S		Controlled Release Tablets	Not Reported
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S		25 Milligram, Ointment	Not Reported
	Cimzia	S	Subcutaneous	Dosage Form: Solution	Not Reported
	Cimzia	S			Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Sulfathalidine	S		Dosage Form: Unspecified	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Oral	20 Milligram	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Oral	1000 Mg, 2x/Day (Bid)	Not Reported
	Sulfasalazine	S	Oral	500 Mg	Not Reported
	Sulfasalazine	S	Oral	1 Dosage Form	Not Reported
	Sulfasalazine	S	Oral	1 Dosage Form, 2x/Day (Bid)	Not Reported
	Sulfasalazine	S	Oral	500 Milligram	Not Reported
	Sulfasalazine	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
	Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
	Sulfasalazine	S	Oral	500 Milligram	Not Reported
	Sulfasalazine	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
	Sulfasalazine	S	Subcutaneous	1 Gram, Once Daily (Qd)	Not Reported
	Sulfasalazine	S	Oral	500 Mg	Not Reported
	Sulfasalazine	S	Oral	1 Dosage Form	Not Reported

Sulfasalazine	S	Oral	1 Dosage Form, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram, Once Daily (Qd)	Not Reported
Sulfasalazine	S		500 Milligram	Not Reported
Sulfasalazine	S		Unk	Not Reported
Apo-Folic Acid	S		5 Mg, Unk	Not Reported
Apo-Hydroxyquine	S		Unk	Not Reported
Apo-Prednisone	S		1 Milligram	Not Reported
Apo-Prednisone	S		5 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Dosage Form: Lyophilized Powder	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Xeljanz	S		5 Mg, 2x/Day (Bid)	Not Reported
Xeljanz	S		5 Mg, 2x/Day (Bid)	Not Reported
Stelara	S		Unk	Not Reported
Prednisone	S	Oral	Dosage Form: Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
Sarilumab	S		Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported

Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Glaxosmithkline
Simponi	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg (0.8 Ml)	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Sunconjunctival	40 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Methotrexate	S	Oral	20 Mg, Once Daily (Qd)	Not Reported
Methotrexate	S	Oral	25 Mg, Unk	Not Reported
Methotrexate	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Methotrexate	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Methotrexate	S	Oral	25 Mg, Unk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Plaquenil	S	Oral	400 Mg, Once Daily (Qd)	Not Reported

	Plaquenil	S	Oral	Unk Unk, Once Daily (Qd)	Not Reported
	Plaquenil	S	Oral	Unk Unk, Once Daily (Qd)	Not Reported
	Plaquenil	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
	Plaquenil	S	Oral	Unk Unk, Once Daily (Qd)	Not Reported
	Plaquenil	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
	Salazopyrin	C		Unk	Not Reported
	Atasol (Acetaminophen)	C		Unk	Not Reported
	Tofacitinib Citrate	C		Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk Unk, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
	Adalimumab	S		Unk	Not Reported
	Golimumab	S		Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Desoximetasone	S	Oral	Cutaneous Route	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	15664903	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2571352-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Humira			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Plaquenil		S	Oral		Not Reported
Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
Remicade		S	Intravenous (not otherwise specified)		Not Reported
Remicade		S	Intravenous (not otherwise specified)		Not Reported
Rituxan		S	Intravenous (not otherwise specified)		Not Reported
Rituxan		S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
Hydroxychloroquine		S	Oral		Not Reported
Hydroxychloroquine		S	Unknown		Not Reported
Hydroxychloroquine		S	Unknown		Not Reported
Rituximab		S	Intravenous (not otherwise specified)		Not Reported
Hydroxychloroquine Sulfate		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	15712495	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587774-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Intravenous (not	Solution Intravenous		Not Reported

		otherwise specified)	
Sulfasalazine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Minocycline	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	15738004	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2595168-00		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Meloxicam			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	16575509	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2852070-00		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Infection; Lower Respiratory Tract	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Diclofenac Sodium/Misoprostol			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis	Simponi	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychoroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Vitamin D3	C		Not Reported
	Ergocalciferol	C		Not Reported
	Colecalciferol	C		Not Reported
	Imuran	C		Not Reported
	Gold	C		Not Reported
	Arthrotec	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	16864058	EXPEDITED (15-DAY)		OT	DE-GILEAD-2019-0424518			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Ambrisentan			S	Unknown	Unk		Gilead
	Roactemra			S	Unknown	162 Mg, Z(Weekly)		Not Reported
	Quensyl			S	Unknown	20 Mg, Bid		Not Reported
	Ramipril			S	Unknown	2.5 Mg, Bid		Not Reported
	Spasmolyt			S	Unknown	15 Mg, Qd		Not Reported
	Eliquis			S	Unknown	2.5 Mg, Bid		Not Reported
	Eliquis			S	Unknown	1 Dosage Form		Not Reported
	Omeprazole			S	Unknown	20 Mg, Bid		Not Reported
	Lyrica			C	Unknown	100 Mg, Tid		Not Reported
	Pregabalin			S	Unknown	100 Mg, Tid		Not Reported

	Sildenafil Citrate			S	Unknown	60 Mg, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	16991114	EXPEDITED (15-DAY)		OT	CA-SA-2019SA303996			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Desoximetasone			S	Oral			Sanofi
	Diclofenac Sodium			S				Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S				Not Reported
	Arava			S	Oral			Sanofi
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S				Not Reported
	Folic Acid			S		1 Mg		Not Reported
	Folic Acid			S		5 Mg		Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Hydroxychloroquine			S				Sanofi
	Methotrexate			S	Intra-arterial	25 Mg		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S				Sanofi
	Pseudoephedrine Hydrochloride			S				Sanofi
	Sulfasalazine			S		500 Mg		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical	25 Mg		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Methotrexate Sodium			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported

Phthalylsulfathiazole	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S			Not Reported
Apo Prednison	S			Not Reported
Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17405411	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-008376		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17579771	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327850		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17579774	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327867		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Off Label Use; Spinal Stenosis; Therapeutic Product Effect Decreased; Unevaluable Event; Urinary Tract Infection	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Prednisone			S	Oral			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Celebrex			C	Unknown			Not Reported
	Gold			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Tofacitinib			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17583352	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		71 YR	Female	CAN

BMS-2020-024371

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Pregabalin			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab;Vorhyaluronidase Alfa			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Piroxicam			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17587303	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200329619			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Mood Altered; Rheumatoid Arthritis	Simponi		S	Subcutaneous	Janssen
	Remicade		S	Intravenous (not otherwise specified)	Janssen
	Prednisone		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17587307	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327870		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Gastric Ulcer; Gastrointestinal Disorder; Haemoptysis; Peptic Ulcer	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17605637	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200333273		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Inflammatory Marker Increased; Pain In Extremity; Sleep Disorder Due To A General Medical Condition	Simponi			S	Subcutaneous			Janssen
	Otezla			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported

	Methotrexate	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17605638	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200333296		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use	Simponi			S	Subcutaneous			Janssen
	Cimzia			S	Subcutaneous	Cimzia Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown	1.0 Dosage Forms		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Oral			Not Reported
	Codeine Phosphate			C	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17641623	EXPEDITED (15-DAY)		HO, OT	EG-ADVANZ PHARMA-202003002270			Unknown	EGY

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Blindness; Blood Glucose Abnormal; Brain Oedema; Loss Of Consciousness	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	2 Dosage Form, Qd		Concordia
	Insulin			C		30 Iu, Qd		Not Reported
	Menthol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17642134	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202003002077			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hip Surgery; Pain	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17642991	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029406		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown	500 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17644154	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1220064		40 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatocellular Injury	Hidroxicloroquina (2143a)	S	Oral	400 Mg / 12 Day 1 Followed By 200 Mg / 12h	Teva
	Hidroxicloroquina (2143a)	S	Oral		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17644417	EXPEDITED (15-DAY)		DE, OT	US-ADVANZ PHARMA-202003002359			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death; Ventricular Fibrillation	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17645665	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2020CA1655		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anti-Neutrophil Cytoplasmic Antibody Positive Vasculitis; Arthralgia; Chest Pain; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Hypersensitivity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Proteinuria; Rheumatoid Arthritis; Treatment Failure; Vasculitis	Anakinra			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Oral			Not Reported
	Azathioprine Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Gold			S	Intramuscular			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Penicillamine	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Docusate Sodium	C	Oral		Not Reported
	Elavil	C	Unknown		Not Reported
	Tobramycin	C	Unknown	0.3% 4x1 Daily	Not Reported
	Cyclophosphamide	C	Intravenous (not otherwise specified)		Not Reported
	Doxycycline	C	Oral		Not Reported
	Prednisone	C	Oral		Not Reported
	Sulfasalazine	C	Oral	1.5 G 2x1 Daily	Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Wellbutrin	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17645724	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009359			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrotic Syndrome	Prednisone			S	Oral	Unk		Not Reported
	Mycophenolate			S	Unknown	Unk		Novartis
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Cellcept /01275102/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17645727	NON-EXPEDITED			NVSC2020US094449		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Rituximab			S	Unknown	Unk		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Colchicine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17646286	EXPEDITED (15-DAY)		DE, OT	US-ADVANZ PHARMA-202003002360			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death; Ventricular Fibrillation	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17646292	EXPEDITED (15-DAY)		DE, OT	US-ADVANZ PHARMA-202003002361			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death; Ventricular Fibrillation	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17646454	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003002357			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Off Label Use; Prostatic Adenoma	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	1 Dosage Form, Qd (Film-Coated Tablet)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17646991	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-028979		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17647436	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3356481-00			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17648751	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3356478-00			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deformity; Movement Disorder; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17649052	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029653			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram, Q6wk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine	C	Unknown	Not Reported
	Wellbutrin	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17649456	DIRECT	Y	DE			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Test Positive	Hydroxychloroquine Sulfate Tablets			S	Oral			Teva
	Oseltamivir Phosphate			C				Not Reported
	Pantoprazole Sodium			C				Not Reported
	Sodium Chloride 0.9% 1000 Ml			C				Not Reported
	Azithromycin 500 Mg			C				Not Reported
	Zosyn 3.375 G			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Atropine			C				Not Reported
	Epinephrine			C				Not Reported
	Acetaminophen			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17649584	NON-EXPEDITED			US-TEVA-2020-US-1213903			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Response Unexpected	Hydroxychloroquine Sulfate			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17649858	NON-EXPEDITED			NVSC2020US093707			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Hydroxychloroquine Sulfate			S	Unknown			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17651020	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029403		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17651063	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-028965			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17651130	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029423		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Sciatica	Orencia			S	Unknown			Bristol Myers Squibb
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown	7 Milligram, Qd		Not Reported
	Apo-Ramipril			S	Unknown	Unk, Qd		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Levothyroxine			S	Unknown	Unk, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

			otherwise specified)			
	Hydroxychloroquine Sulfate	C	Unknown	400 Milligram, Qd		Not Reported
	Acetaminophen, Caffeine, Dihydrocodeine Bitartrate	C	Unknown			Not Reported
	Acetaminophen;Codeine	C	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C	Ophthalmic	Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17651159	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029452			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17651582	DIRECT	Y	OT			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral			Not Reported
	Amiodarone			S	Oral			Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	11257960	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-046061		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Phosphate			S	Unknown			Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Kineret			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Gold			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

Celebrex	S	Unknown	Unk		Not Reported
Methotrexate Sodium	S	Unknown	1 Ml, Qwk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Prednisone	S	Intravenous (not otherwise specified)	7 Mg, Qd		Not Reported
Apo-Leflunomide	S	Unknown			Not Reported
Apo-Hydroxyquine	S	Unknown			Not Reported
Apo-Mycophenolic Acid	S	Unknown			Not Reported
Methotrexate	S	Unknown	1 Milliliter		Not Reported
Methotrexate	S	Unknown	20 Milligram		Not Reported
Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
Cellcept [Mycophenolate Mofetil]	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown			Not Reported
Rituximab	S	Unknown			Not Reported
Xeljanz	C	Oral	5.0 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	13064952	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20161217720			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Drug Ineffective; Joint Injury; Knee Arthroplasty; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Urticaria	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported

	Ibuprofen	C	Unknown	Not Reported
	Morphine	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Pertussis Vaccine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	14501669	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007157		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Fall; Fatigue; Femur Fracture; Haematocrit Decreased; Haemoglobin Decreased; Impaired Healing; Joint Swelling; Multiple Fractures; Musculoskeletal Pain; Off Label Use; Osteoporosis; Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Apo-Folic Acid			S	Unknown	5 Milligram, 2 Times/Wk		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Bid		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Bid		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Co Atenolol			S	Unknown	25 Milligram, Qd		Not Reported
	Co Atenolol			S	Unknown	20 Milligram, Qd		Not Reported
	Atenolol			S	Unknown	25 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Q2wk		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Q2wk		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	25 Milligram		Not Reported
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Not Reported
	Naprosyne			S	Oral	1000 Milligram, Qd		Not Reported

Naprosyne	S	Oral	100 Milligram, Qd	Not Reported
Naprosyne	S	Oral	500 Milligram, Bid	Not Reported
Palafer Cf	S	Unknown	1 Dosage Form, 1 Every 24 Hrs	Not Reported
Pantoloc [Pantoprazole Sodium Sesquihydrate]	S	Unknown	40 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	40 Milligram, Qd	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	40 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	40 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Ascorbic Acid	S	Unknown	Unk Unk, Qd	Not Reported
Actemra	S	Unknown		Not Reported
Naproxen Sodium	S	Oral	500 Milligram, Bid	Not Reported
Naproxen Sodium	S	Unknown	100 Milligram, Qd	Not Reported
Naproxen Sodium	S	Unknown	1000 Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Ferrous Fumarate	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	25 Milligram, Q2wk	Not Reported
Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	20 Milligram, Q2wk	Not Reported
Methotrexate	S	Oral	20 Milligram, Cyclical	Not Reported
Naproxen	S	Oral	500 Milligram, Bid	Not Reported

Naproxen	S	Oral	100 Milligram, Qd	Not Reported
Naproxen	S	Oral	1000 Milligram, Qd	Not Reported
Celecoxib	S	Unknown		Not Reported
Folic Acid	S	Unknown	5 Milligram, Q2wk	Not Reported
Folic Acid	S	Unknown	5 Milligram, Bid	Not Reported
Folic Acid	S	Unknown	400 Milligram	Not Reported
Folic Acid	S	Unknown	5 Unk	Not Reported
Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram, Qwk	Not Reported
Hydroxychloroquine	S	Unknown	40 Unk	Not Reported
Ferrous Fumarate;Folic Acid	S	Unknown	Unk Unk, Qd	Not Reported
Xeljanz	S	Unknown		Not Reported
Pantoprazole	S	Unknown	40 Milligram, Qd	Not Reported
Pantoprazole Sodium Anhydrous	S	Unknown	40 Milligram, Qd	Not Reported
Methotrexate	S	Oral	20 Milligram, Q2wk	Not Reported
Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported
Naprosyn [Naproxen Sodium]	S	Oral	1000 Milligram, Qd	Not Reported
Naprosyn [Naproxen Sodium]	S	Oral	500 Milligram, Bid	Not Reported
Naprosyn [Naproxen Sodium]	S	Oral	100 Milligram, Qd	Not Reported
Etanercept	S	Subcutaneous	Unk	Not Reported
Palafer	S	Unknown	Unk	Not Reported
Teva Pantoprazole	S	Unknown	40 Milligram, Qd	Not Reported
Vitamin C [Ascorbic Acid]	S	Unknown	Unk, Qd	Not Reported
Pantoprazole Sodium	S	Unknown	40 Milligram, Qd	Not Reported
Celebrex	C	Oral	200 Milligram, Qd	Not Reported
Celecoxib	C	Oral	200 Milligram, Qd	Not Reported
Prednisone	C	Intracardiac	5 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	14750177	EXPEDITED (15-DAY)		DE, OT	IT-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-031026		67 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Death; Drug Interaction; Haemoptysis; International Normalised Ratio Decreased; Labelled Drug-Drug Interaction Medication Error; Platelet Count Decreased; Product Administration Error; Pyrexia	Warfarin Sodium			S	Unknown	Unk		Bristol Myers Squibb
	Aspirin			S	Unknown	Unk		Bristol Myers Squibb
	Influenza Vaccine			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Montelukast			S	Unknown	Unk		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Asa			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	15219753	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-NODEN PHARMA DAC-NOD-2018-000052			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Product Monitoring Error; Truncus Arteriosus Persistent; Ventricular Septal Defect	Rasilez			S	Transplacental	300 [Mg/D]; 0-4.6 Gestational Week		Noden Pharma
	Rasilez			S				Noden Pharma
	Prednisolone			S	Transplacental	From Gestational Week 0-14		Not Reported
	Prednisolone			S	Transplacental	Unk		Not Reported
	Salbutamol Sulfate			S	Transplacental	Unk, If Required; Trimester: First+Second;From Gestational Week 0-14		Not Reported
	Salbutamol Sulfate			S	Transplacental	Unk		Not Reported
	Delix /00885601/			S	Transplacental	Maternal Dose 20 Mg, Qd (Exposure Duration 0-		Not Reported

			13+6 Weeks)	
Delix /00885601/	S			Not Reported
Quensyl	S	Transplacental	400 [Mg/D (2x200)]; 0-13.6 Gestational Week;From Gestational Week 0-14	Not Reported
Quensyl	S	Transplacental	Unk	Not Reported
Acetylsalicylic Acid	S	Transplacental	From Gestational Week 0-14	Not Reported
Acetylsalicylic Acid	S	Transplacental	From Gestational Week 0-14	Not Reported
Acetylsalicylic Acid	S			Not Reported
Pantozol /01263204/	S	Transplacental	40 [Mg/D]; 0-13.6 Gestational Week;From Gestational Week 0-14 (Busco Pantoprazole)	Not Reported
Pantozol /01263204/	S	Transplacental	Unk	Not Reported
Torasemide	S	Transplacental	From Gestational Week 0-14	Not Reported
Torasemide	S	Transplacental	Unk	Not Reported
Advagraf	S	Transplacental	6 [Mg/D]; 0-13.6 Gestational Week, From Gestational Week 0-14	Not Reported
Advagraf	S	Transplacental	Unk	Not Reported
Advagraf	S			Not Reported
Nicotine	S	Transplacental	From Gestational Week 0-14	Not Reported
Nicotine	S	Transplacental	Unk	Not Reported
Ezetimibe Msd	S	Transplacental	From Gestational Week 0-14	Not Reported
Novaminsulfon	S	Transplacental	Exposure Duration: 0-14 Weeks. Trimester: First; Probably Only In Hospital In Week 5.	Not Reported
Novaminsulfon	S	Transplacental	Unk; Trimester: First; Probably Only In Hospital	Not Reported

				In Week 5	
	Novaminsulfon	S	Transplacental	300 Milligram, Qd	Not Reported
	Simvastatin	S	Transplacental	From Gestational Week 0-14	Not Reported
	Xarelto	S	Transplacental	From Gestational Week 0-5	Not Reported
	Clexane	S	Transplacental	200 Milligram, Qd	Not Reported
	Clexane	S	Transplacental	200 Mg/D (2x100)	Not Reported
	Clexane	S			Not Reported
	Heparin Lmw	S	Transplacental	Unknown	Not Reported
	Heparin Lmw	S			Not Reported
	Enoxaparin	S	Transplacental	From Gestational Week 0-14	Not Reported
	Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported
	Rituximab	S	Transplacental	Unk	Not Reported
	Heparin	S	Transplacental	Unk (Low Molecular Weight Heparin)	Not Reported
	Cytotec	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
	Mifegyne	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
	Cyclophosphamide	C	Transplacental	3000 [Mg Cumulative]; Preconceptional	Not Reported
	Cyclophosphamide	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	15551940	EXPEDITED (15-DAY)		CA	DE-TEVA-2018-DE-967934			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Truncus Arteriosus Persistent;	Tacrolimus			S	Transplacental			Actavis
	Torem			S	Transplacental	100 [Mg/D]		Not Reported

Ventricular Septal Defect	Quensyl	S	Transplacental	200 Milligram Daily; Daily Dose: 400 Mg Millgram(S) Every Days	Not Reported
	Rituximab	S	Transplacental	Last Time In December 2011: Pre Or Periconceptional	Not Reported
	Inegy	S	Transplacental	40 [Mg/D] / 10 [Mg/D]	Not Reported
	Delix (Ramipril)	S	Transplacental	20 [Mg/D]	Not Reported
	Advagraf	S	Transplacental	6 [Mg/D]	Not Reported
	Pantozol	C	Transplacental	40 [Mg/D]	Not Reported
	Albuterol	C	Transplacental	Unk, Prn	Not Reported
	Cytotec	C	Transplacental	Unk	Not Reported
	Cyclophosphamid	C	Transplacental	3000 [Mg Cumulative]/ April -August 2011	Not Reported
	Xarelto 10 Mg Filmtabletten	C	Transplacental	Not Known, If Treatment Started Before Or After Missed Abortion.	Not Reported
	Clexane	C	Transplacental	200 [Mg/D (2x100)]	Not Reported
	Novaminsulfon	C	Unknown	For 5 Weeks	Not Reported
	Aliskiren	C	Transplacental	300 [Mg/D]	Not Reported
	Mifegyne	C	Transplacental	Unk	Not Reported
	Rasilez	C	Transplacental	300 [Mg/D]	Not Reported
	Salbutamol	C	Transplacental	If Required	Not Reported
	Prednisolon	C	Transplacental	Daily Dose: 10 Mg Milligram(S) Every 2 Day	Not Reported
	Ass	C	Transplacental	100 [Mg/D]	Not Reported
	Novaminsulfon	C	Transplacental	Probably Only In Hospital In Week 5	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	15623961	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557378-00		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Event; Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Multiple Allergies; Multiple Allergies; Musculoskeletal Pain; Musculoskeletal Pain; Off Label Use; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event	Humira	S	Subcutaneous		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Actemra	S			Not Reported
	Arava	S	Oral		Not Reported
	Cellcept	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Lyrica	S	Oral		Not Reported
	Lyrica	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Mycophenolate Mofetil Hydrochloride	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo Mycophenolate	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Sodium Aurothiomalate	S	Oral		Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Cyclosporine	S	Oral		Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported

Cimzia	S	Subcutaneous	Not Reported
Certolizumab Pegol	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Piroxicam	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Pregabalin	S	Oral	Not Reported
Teva Mycophenolate	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Piroxicam	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	15635156	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105525		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Subcutaneous	750 Milligram, Qwk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Gram, Q2wk		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown	2000 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Parenteral	Unk		Not Reported
	Rituxan			S	Intravenous (not	2000 Milligram		Not Reported

					otherwise specified)				
	Sulfasalazine			S	Unknown	Unk			Not Reported
	Xeljanz			C	Oral	Unk Unk, Q2wk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	15957810	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190213510			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Janssen
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17533403	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200243621		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Crohn'S Disease; Drug Hypersensitivity; Drug Ineffective; Lower	Stelara			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen

Respiratory Tract Infection; Nasopharyngitis; Off Label Use; Product Use In Unapproved Indication	Simponi		S	Subcutaneous		Janssen
	Gabapentin		S	Unknown		Not Reported
	Perindopril		S	Unknown		Not Reported
	Cimzia		S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Cosentyx		S	Unknown		Not Reported
	Etanercept		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Otezla		S	Unknown		Not Reported
	Plaquenil /00072602/		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17558247	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200316516		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tocilizumab			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Desoximetasone	C		Not Reported
	Methotrexate Sodium	C	Oral	Not Reported
	Prednisone	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17577764	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200329945			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Infection; Joint Swelling; Liver Function Test Increased; Pain; Paralysis; Skin Infection; Treatment Failure; Urinary Tract Infection	Simponi			S	Subcutaneous			Janssen
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Diphenhydramine			C	Oral			Not Reported
	Hydroxychloroquine			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17577767	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200329960			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated	Simponi			S	Subcutaneous			Janssen

Product Administered; Drug Ineffective; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Apo-Leflunomide	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tofacitinib	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Sarilumab	S			Not Reported
	Leflunomide	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Rabeprazole Sodium	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17605627	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332798			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Simponi			S	Subcutaneous			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

Methotrexate	S	Subcutaneous		Not Reported
Orencia	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Cimzia	C	Subcutaneous		Not Reported
Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17605642	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332799		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Intolerance; Herpes Zoster; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1.0 Dosage Forms		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17605650	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332795		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Simponi			S	Subcutaneous			Janssen
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Ergocalciferol			C				Not Reported
	Folinic Acid			C				Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17605716	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332774			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Incomplete	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17611318	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20160614521			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Hereditary Angioedema; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Remicade			S	Intravenous (not otherwise specified)	Ndc: 412545		Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

	Prevacid	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17623404	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200342106		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17623464	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340472		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use	Simponi			S	Subcutaneous			Janssen
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naprosyn /00256201/			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17647143	EXPEDITED (15-DAY)		HO, LT, OT	MX-ALKEM LABORATORIES LIMITED-MX-ALKEM-2020-01066		29 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Abscess; Endophthalmitis; Liver Abscess; Muscle Abscess; Myositis; Nocardiosis; Perinephric Abscess; Pneumonia; Pyomyositis	Mycophenolate Mofetil			S	Oral	2.5 Gram, Qd		Alkem
	Hydroxychloroquine			S	Oral	200 Milligram, Qd		Not Reported
	Prednisone			S	Oral	30 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17648078	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029659		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk Unk, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	22.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Parenteral	25 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

Sulfasalazine	S	Unknown	500 Milligram		Not Reported
Tocilizumab	C	Unknown	Unk		Not Reported
Azathioprine	C	Unknown	Unk, Qd		Not Reported
Ciclosporin	C	Unknown	Unk		Not Reported
Minocycline	C	Unknown	Unk		Not Reported
Penicillamine	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17648606	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029670		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Infection; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qh		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	175 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Risedronate Sodium			S	Unknown	35 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Milligram		Not Reported

	Simponi	S	Subcutaneous	Not Reported
	Risedronate	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17648737	EXPEDITED (15-DAY)		OT	DE-GLAXOSMITHKLINE-DE2020061233		42 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis; Erythema Nodosum; Herpes Dermatitis; Herpes Simplex; Immune Reconstitution Inflammatory Syndrome; Immune Reconstitution Inflammatory Syndrome; Lymphoedema; Mass; Nodule; Panniculitis; Papilloma Viral Infection; Periorbital Oedema; Periorbital Swelling	Ceftriaxone Sodium			S	Unknown	Unk		Glaxosmithkline
	Streptomycin			S	Unknown	Unk		Glaxosmithkline
	Cotrimoxazole			S	Unknown	Unk		Glaxosmithkline
	Sulfamethoxazole + Trimethoprim			S	Unknown	Unk		Glaxosmithkline
	Sulfamethoxazole + Trimethoprim			S	Unknown	960 Mg, Qd		Glaxosmithkline
	Ceftriaxone			S	Unknown	Unk		Glaxosmithkline
	Azathioprine			S	Unknown	Unk		Glaxosmithkline
	Acyclovir			S	Unknown	Every 4 Hours.		Glaxosmithkline
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Dose Increased		Not Reported
	Prednisone			S	Unknown	Dose Reduced		Not Reported
	Doxycycline			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17648841	EXPEDITED (15-DAY)		HO	US-ADVANZ PHARMA-202003002755			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Malaise; Off Label Use	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17649603	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1219671		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Gabapentin			S	Oral			Actavis
	Fentanyl			S	Unknown			Cephalon
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2.5 Gram Daily;		Not Reported
	Acetaminophen			C				Not Reported
	Aclasta			C				Not Reported
	Docosahexaenoic Acid/Eicosapentaenoic Acid			C				Not Reported
	Nasonex			C				Not Reported
	Prednisone			C				Not Reported
	Trazodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17651306	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029788			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported

Enbrel	S	Unknown	25 Milligram		Not Reported
Humira	S	Subcutaneous	40 Milligram		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid		Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd		Not Reported
Methotrexate	S	Unknown	20 Milligram, Qwk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	C	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported
Bupropion	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17652023	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020146043			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Off Label Use; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Renal Impairment	Methotrexate Sodium			S	Oral			Pfizer
	Methotrexate Sodium			S	Subcutaneous			Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17652025	EXPEDITED (15-DAY)		OT	RO-ADVANZ PHARMA-202003002774			Unknown	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17652040	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004002411			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Eosinophilic Myocarditis; Exposure During Pregnancy; Rash	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17652041	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201909000624			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Depression; Drug Ineffective; Drug Intolerance; Hypersensitivity; Myelopathy; Neuropathy Peripheral	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Pyridoxine Hydrochloride			S	Unknown	Unk		Not Reported
	Lasix			C		Unk		Not Reported
	Xarelto			C		Unk		Not Reported
	Vitamin B12 Nos			C		Unk		Not Reported
	Calcium			C		Unk		Not Reported
	Bisoprolol			C		Unk		Not Reported
	Fish Oil			C		Unk		Not Reported
	Magnesium			C		Unk		Not Reported
	Ramipril			C		Unk		Not Reported
	Buprenorphine			C		Unk		Not Reported
	Vitamin D			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Vitamin B6			C		Unk		Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17652062	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1220063		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Gabapentin			S	Unknown	200 Milligram Daily;		Actavis
	Fentanyl			S	Unknown			Cephalon
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Intravenous (not otherwise specified)	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2.5 Gram Daily;		Not Reported
	Aclasta			C	Intravenous (not otherwise specified)			Not Reported
	Ascorbic Acid			C	Unknown			Not Reported
	Biotin			C				Not Reported
	D-Alpha Tocopherol			C	Unknown	2400 Milligram Daily;		Not Reported
	Diphenoxylate Hydrochloride			C	Unknown	2.5 Milligram Daily;		Not Reported
	Diphenoxylate Hydrochloride			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown	400 Iu (International Unit) Daily;		Not Reported
	Esomeprazole			C	Unknown	80 Milligram Daily;		Not Reported

Ferrous Fumarate	C	Unknown		Not Reported
Folic Acid	C			Not Reported
Hydroxocobalamin	C			Not Reported
Loperamide Hydrochloride	C	Unknown		Not Reported
Nasonex	C	Unknown	4 Dosage Forms Daily;	Not Reported
Nicotinamide	C			Not Reported
Nortriptyline Hydrochloride	C	Oral	40 Milligram Daily;	Not Reported
Nortriptyline Hydrochloride	C	Oral		Not Reported
Prednisone	C	Unknown	5 Gbq Daily;	Not Reported
Pyridoxine Hydrochloride	C			Not Reported
Riboflavin	C			Not Reported
Risedronate Sodium	C	Unknown		Not Reported
Sodium Ascorbate	C			Not Reported
Thiamine Hydrochloride	C			Not Reported
Thiamine Mononitrate	C			Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram Daily;	Not Reported
Tylenol	C	Unknown	1000 Milligram Daily;	Not Reported
Vitamin A	C			Not Reported
Vitamin C [Ascorbic Acid]	C			Not Reported
Vitamin D3	C			Not Reported
Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17652287	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1036031		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Furosemide			S		Unk		Not Reported
	Dabigatran Etexilate			S	Oral	300 Milligram, Qd		Mylan
	Daparox /00830803/			S		Unk		Mylan
	Lamictal			S		Unk		Mylan
	Plaquenil /00072602/			S		Unk		Mylan
	Valium			S		Unk		Mylan
	Sotalol			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17654933	DIRECT	Y	DE			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Endotracheal Intubation Complication	Hydroxychloroquine			S	Oral			Teva
	Hydroxychloroquine			S	Oral			Teva
	Azithromycin			C				Not Reported
	Albuterol			C				Not Reported
	Lasix			C				Not Reported
	Zosyn			C				Not Reported
	Humulin R			C				Not Reported
	Vancomycin			C				Not Reported
	Lovenox			C				Not Reported
	Tamiflu			C				Not Reported
	Rocephin			C				Not Reported
	Acetaminophen			C				Not Reported
	Zofran			C				Not Reported
	Ns			C				Not Reported
	D50w			C				Not Reported
	Pravachol			C				Not Reported
	Ativan			C				Not Reported
	Doxycycline			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	15635730	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1478917-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Enbrel	S	Subcutaneous			Not Reported
Methotrexate Sodium	S	Oral			Not Reported
Orencia	S	Intravenous (not otherwise specified)	3 Years		Not Reported
Plaquenil	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Hydroxychloroquine	S	Subcutaneous			Not Reported
Apo-Hydroxyquine	S	Subcutaneous			Not Reported
Apo-Azathioprine	S	Unknown			Not Reported
Methotrexate	S	Subcutaneous			Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	16946977	EXPEDITED (15-DAY)		LT, OT	CA-GLAXOSMITHKLINE-CA2019AMR190534		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Fatigue; Off Label Use; Suicidal Ideation	Benlysta			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Glaxosmithkline
	Benlysta			S		Unk		Glaxosmithkline
	Benlysta			S		Unk		Glaxosmithkline
	Benlysta			S		Unk		Glaxosmithkline
	Benlysta			S		200 Mg		Glaxosmithkline
	Benlysta			S	Subcutaneous	Unk		Glaxosmithkline
	Imuran			S	Oral	200 Mg, Qd		Glaxosmithkline
	Plaquenil			S		400 Mg, Qd		Not Reported
	Prednisone			S		20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17395563	NON-EXPEDITED			US-AMGEN-USASP2020020542		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17653559	NON-EXPEDITED		OT	US-SA-2020SA089843			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction	Arava			S				Sanofi
	Plaquenil			S				Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17653880	EXPEDITED (15-DAY)		DE	FR-TEVA-2020-FR-1221561		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Ebilfumin 75 Mg, Gélule			S	Oral	75 Mg		Teva
	Ceftriaxone Mylan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Plaquenil			S	Oral	At D1 Then 400mg / Day, Unit Dose: 800 Mg		Not Reported
	Coversyl 5 Mg, Comprimé Pelliculé Sécable			C	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17654641	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030070		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea;	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb

Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17654647	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029994			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Orencia			S	Unknown			Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varicella Zoster Vaccine Live			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Diclofenac			C	Oral	100 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17654650	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030021		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	200 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	5 Milligram		Not Reported
	Leflunomide			S	Oral	5 Milligram		Not Reported
	Methotrexate			S	Unknown	5 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Milligram, 2 Every 1 Day		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17654666	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1221569			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Nightmare; Product Use In Unapproved Indication; Psychomotor Hyperactivity	Azithromycine Dihydratee			S	Oral	500 Mg		Not Reported
	Plaquenil 200 Mg, Comprime Enrobe			S	Oral	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17654748	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3357368-00		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hepatocellular Injury	Kaletra 200/50			S	Oral	2 Comp/12h		Not Reported

	Kaletra 200/50	S				Not Reported
	Ceftriaxona	S	Intravenous (not otherwise specified)	2gr/24h		Not Reported
	Ceftriaxona	S				Not Reported
	Hidroxicloroquina	S	Oral	200mg/12h		Not Reported
	Hidroxicloroquina	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17654834	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020146015			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuropathy Peripheral	Methotrexate Sodium			S	Unknown			Pfizer
	Celebrex			S	Unknown			Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Xeljanz			S	Unknown			Pfizer
	Codeine Phosphate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Azathioprine Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17655309	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003002613			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Fatigue; Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Triatec [Ramipril]			C				Not Reported
	Doliprane			C				Not Reported
	Levothyrox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17655685	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1219067		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Ciclosporin			S	Unknown			Ivax
	Ciclosporin			S	Unknown			Ivax
	Alendronate Sodium			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Ibuprofen			S	Oral			Actavis
	Ibuprofen			S	Oral	600 Milligram Daily;		Actavis
	Ibuprofen			S	Oral			Actavis
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Apo-Ibuprofen			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apremilast			S	Unknown			Not Reported
	Apremilast			S	Unknown	120 Milligram Daily;		Not Reported
	Apremilast			S				Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported

Orencia	S	Unknown			Not Reported
Otezla	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)	2000 Milligram Daily;		Not Reported
Simponi	S	Subcutaneous			Not Reported
Stelara	S	Subcutaneous			Not Reported
Sulfasalazine	S	Endocervical			Not Reported
Tocilizumab	S	Unknown			Not Reported
Tocilizumab	S	Unknown			Not Reported
Benadryl	C				Not Reported
Colchicine	C	Oral			Not Reported
Dexilant	C				Not Reported
Febuxostat	C				Not Reported
Folic Acid	C				Not Reported
Gravol	C				Not Reported
Mogadon	C	Oral			Not Reported
Nitrazepam	C	Unknown			Not Reported
Oxycodone	C				Not Reported
Prednisone	C				Not Reported
Uloric	C	Unknown	160 Milligram Daily;		Not Reported
Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17655811	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1220302		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug	Amlodipine Besilate			S	Oral	5 Milligram Daily;		Teva
	Amlodipine Besilate			S	Oral			Teva
	Gliclazide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr

Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Methotrexate	S	Subcutaneous		Barr
	Asacol	S	Unknown	2400 Milligram Daily;	Not Reported
	Diamicron	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Acetaminophen	C	Oral		Not Reported
	Atacand Plus	C			Not Reported
	Bisoprolol Fumarate	C			Not Reported
	Diphenhydramine	C	Oral		Not Reported
	Ferrous Gluconate	C			Not Reported
	Folic Acid	C			Not Reported
	Methylprednisolone Acetate	C	Intravenous (not otherwise specified)		Not Reported
	Methylprednisolone Acetate	C	Intra-articular		Not Reported
	Rosuvastatin Calcium	C			Not Reported
	Tylenol	C			Not Reported
	Vitamin D3	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17655893	EXPEDITED (15-DAY)		OT	BR-ADVANZ PHARMA-202003002355			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence	Hydroxychloroquine			S	Unknown	(Strength: 400mg 2x15 Cprrev		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17656013	EXPEDITED (15-DAY)		OT	GR-PBT-000004		68 YR	Unknown	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatomyositis; Disease Progression; Drug Ineffective; Product Use In Unapproved Indication; Vasculitic Rash	Tacrolimus			S	Unknown			Panacea Biotec
	Tacrolimus			S	Unknown			Panacea Biotec
	Thiamazole			C	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Intraocular	200mg Oculus Dexter (Od)		Not Reported
	Hydroxychloroquine			S	Intraocular	200mg Oculus Dexter (Od)		Not Reported
	Hydroxychloroquine			S	Unknown	Dose Was Doubled		Not Reported
	Hydroxychloroquine			S	Unknown	Dose Was Doubled		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	Intravenous Pulse (1 Gr).		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	Intravenous Pulse (1 Gr).		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	Intravenous Pulse		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	Intravenous Pulse		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	Two Monthly Intravenous Pulses		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown	Two Weeks Apart		Not Reported
	Rituximab			S	Unknown	Two Weeks Apart		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17656614	DIRECT	Y	OT			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17656633	DIRECT		OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Dyspnoea	Hydroxychloroquine	Y		S	Oral	Quantity:10 Tablet(S);		Not Reported
	Breo			C				Not Reported
	Dupixent			C				Not Reported
	Green Tea			C				Not Reported
	Magnesium			C				Not Reported
	Black Seed Oil			C				Not Reported
	Blessed Thistle			C				Not Reported
	Sunflower Lecithin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17657153	EXPEDITED (15-DAY)		OT	PL-AMNEAL PHARMACEUTICALS-2020-AMRX-01107		54 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2x/Day		Amneal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17657180	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1220398		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia;	Amlodipine Besilate			S	Oral	5 Milligram Daily;		Teva
	Gliclazide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported

Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Orencia	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Asacol Also Known As Mesalamine	S	Unknown	2400 Milligram Daily;	Not Reported
	Xeljanz	S	Unknown		Not Reported
	Diamicron	S	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported
	Vitamin D3	C	Unknown		Not Reported
	Acetaminophen	C	Oral		Not Reported
	Diphenhydramine	C	Oral		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)		Not Reported
	Atacand Plus	C	Unknown		Not Reported
	Bisoprolol Fumarate	C	Unknown		Not Reported
	Depo-Medrol	C	Intra-articular		Not Reported
	Ebastine	C	Unknown		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17657558	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1220718			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Ramipril			S	Oral			Actavis
	Ramipril			S	Unknown			Actavis
	Acetaminophen			S	Unknown			Not Reported
	Dorzolamide/Timolol			S	Unknown	2 Dosage Forms Daily;		Actavis
	Dorzolamide/Timolol			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis

Methotrexate	S	Unknown			Barr
Actemra	S	Unknown			Not Reported
Folic Acid	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
Levothyroxine	S	Unknown			Not Reported
Levothyroxine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	15401123	EXPEDITED (15-DAY)		OT	DE-ABBVIE-18K-062-2483634-00		63 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Ciclosporin			S	Subcutaneous			Not Reported
	Ciclosporin			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Neoral			S	Oral			Not Reported
	Neoral			S	Oral			Not Reported

Apo-Hydroxyquine	S	Oral		Not Reported
Apo-Hydroxyquine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Apo-Leflunomide	S	Oral	Tablet	Not Reported
Apo-Leflunomide	S	Oral	Tablet	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous Rituxan	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Methotrexat	S	Subcutaneous	20mg	Not Reported
Methotrexat	S	Oral	20mg, Solution For Injection/Infusion	Not Reported
Methotrexate Sodium	S	Oral	20 Mg	Not Reported
Methotrexate Sodium	S	Subcutaneous	20mg	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw Txt	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw Txt	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg Powder For Solution Intravenous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg Powder For Solution Intravenous	Not Reported
Leflunomide	S	Unknown	Film Coated Tablet	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous		Not Reported
Xeljanz	C	Unknown	2 Ot, Qd	Not Reported
Xeljanz	C	Oral	10 Mg, Qd (5 Mg, Bid)	Not Reported
Xeljanz	C	Oral	2 Ot, Qd	Not Reported
Xeljanz	C	Unknown	2 Ot, Qd	Not Reported

	Xeljanz		C	Oral	10 Mg, Qd (5 Mg, Bid)	Not Reported
	Xeljanz		C	Oral	2 Ot, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	15621780	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2557337-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Hospitalisation; Infection; Limb Discomfort; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cefazolin			S	Intramuscular			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Viread			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	16079912	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-06123		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Off Label Use; Red Blood Cell Sedimentation Rate Increased; Urticaria	Infliximab			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Single Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown, Solution		Not Reported
	Humira			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Oral	Unknown		Not Reported
	Plaquenil			S	Oral	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituxan			S	Subcutaneous	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown, Solution		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Abatacept			S	Unknown	Unknown		Not Reported
	Rituximab			S	Intravenous (not	Unknown		Not Reported

			otherwise specified)		
	Rituximab	S	Subcutaneous	Unknown	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Unknown	Not Reported
	Leflunomide	S	Oral	Unknown	Not Reported
	Actemra	C	Unknown	Unknown	Not Reported
	Azathioprine	C	Unknown	Unknown	Not Reported
	Ciclosporin	C	Unknown	Unknown	Not Reported
	Minocycline	C	Unknown	Unknown	Not Reported
	Penicillamine	C	Unknown	Unknown	Not Reported
	Prednisone	C	Unknown		Not Reported
	Tocilizumab	C	Unknown	Unknown	Not Reported
	D-Penicillamine	C	Unknown	Unknown	Not Reported
	Prednisolone	C	Unknown		Not Reported
	Cyclosporin	C	Unknown	Unknown	Not Reported
	Phenylbutazone	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	17658279	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS INC.-2020-01638		31 YR	Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	17658282	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS INC.-2020-01639		42 YR	Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	17658365	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2762682-00		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Drug Ineffective; Drug Ineffective; Gout; Loss Of Personal Independence In Daily Activities; Metabolic Disorder; Metabolic Surgery; Middle Insomnia; Musculoskeletal Stiffness; Off Label Use; Pain In Extremity; Product Use Issue; Synovitis; Weight Increased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Allopurinol			C				Not Reported
	Pantoloc			C	Unknown			Not Reported
	Zyloprim			C				Not Reported
	Clomipramine			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	17658388	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020014951			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Apo-Leflunomide			S		20 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S		200 Milligram		Not Reported
	Methotrexate			S		20 Milligram		Not Reported
	Orencia			S		Unk		Not Reported

Sulfasalazine	S		1 Gram		Not Reported
Xeljanz	C	Oral	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	17658450	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030120			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Orencia			S	Unknown			Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported
	Desoximetasone			C	Oral			Not Reported
	Diclofenac			C	Unknown	100 Milligram		Not Reported
	Xeljanz			C	Oral	5 Milliliter, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	12776517	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076645		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Off	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb

Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Arava		S	Unknown	Unk		Not Reported
	Enbrel		S	Subcutaneous	Unk		Not Reported
	Humira		S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine		S	Unknown	Unk		Not Reported
	Methotrexate		S	Subcutaneous	Unk		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi		S	Subcutaneous	Unk		Not Reported
	Sulfasalazine		S	Unknown	Unk		Not Reported
	Hydroxychloroquine		S	Unknown	Unk		Not Reported
	Gold		S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate		S	Subcutaneous	Unk		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab		S	Intravenous drip	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	14778692	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009922			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Hepatitis; Therapeutic Response Decreased	Hydroxychloroquine			S	Oral	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Methotrexate			C	Unknown	20 Mg, Q.Wk.		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	15624165	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556702-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Wellbutrin			C	Unknown	Extended Release		Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Bupropion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	15686123	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573639-00		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Injection Bp		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Gold	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Acetaminophen	C			Not Reported
Anakinra	C	Unknown		Not Reported
Ativan	C			Not Reported
Codeine	C	Unknown		Not Reported
Darifenacin	C			Not Reported
Desoximetasone	C	Oral		Not Reported
Desoximetasone	C	Intramuscular		Not Reported
Dilaudid	C	Unknown		Not Reported
Diphenhydramine	C			Not Reported
Furosemide	C			Not Reported
Hydromorphone	C	Unknown		Not Reported
Kadian	C		Sustained-Release	Not Reported
Kenalog	C	Intra-articular		Not Reported
Kenalog	C			Not Reported
Loperamide	C	Unknown		Not Reported
Norflex	C	Unknown		Not Reported
Omnaris	C	Unknown	Spray,Metered Dose	Not Reported
Oxyneo	C	Unknown	Extended Release	Not Reported
Pantoprazole Sodium	C			Not Reported
Restasis	C	Unknown		Not Reported
Rituxan	C	Intravenous (not otherwise specified)		Not Reported
Synthroid	C	Unknown		Not Reported
Trimethoprim	C	Unknown		Not Reported

Urispas	C			Not Reported
Vagifem	C	Vaginal		Not Reported
Dexamethason	C	Intramuscular		Not Reported
Dyclonine Hydrochloride	C			Not Reported
Enablex	C		(Extended Release)	Not Reported
Pantoprazole Sodium Anhydrous	C			Not Reported
Lasix	C			Not Reported
Morphine Sulphate	C	Unknown		Not Reported
Dyclone	C			Not Reported
Benadryl	C	Unknown		Not Reported
Diphenhydramine Hydrochloride	C	Unknown		Not Reported
Darifenacin Hydrobromide	C	Unknown		Not Reported
Pantoprazole	C	Unknown		Not Reported
Pantoloc	C			Not Reported
Triamcinolone Acetonide	C	Intra-articular		Not Reported
Dexamethasone	C	Unknown		Not Reported
Orphenadrine Citrate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	15708189	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2586143-00		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Hypersensitivity; Incorrect Route Of Product Administration; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Varicella Zoster Vaccine			S	Unknown	Liquid Intramuscular		Not Reported

	Etanercept	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous drip	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	15713147	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2588025-00		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Contraindicated Product Administered; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Humira			S	Subcutaneous			Not Reported
	Arava			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquin			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	15848951	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633323-00		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension;	Humira			S	Subcutaneous			Not Reported

Adverse Drug Reaction; Drug Ineffective; Dyspepsia; Gastric Disorder; General Physical Health Deterioration; Insomnia; Nausea; Rheumatoid Arthritis; Sleep Disorder	Actemra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Myochrysine	S	Parenteral	Not Reported
	Otezla	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Salazopyrin	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sirukumab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Ustekinumab	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Minocycline	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Orencia	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	15923770	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2653534-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Arthralgia;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported

Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Codeine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported

Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Sulfasalazine	S	Intramuscular	Not Reported
Sulfasalazine	S	Intramuscular	Not Reported
Sulfasalazine	S	Parenteral	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous drip	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Alendronic Acid	S	Unknown	Not Reported
Myochrysine	S	Unknown	Not Reported
Ciclosporin	C		Not Reported
Prednisone	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Ciclosporin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	15932948	EXPEDITED (15-DAY)		HO, LT, OT	CA-ABBVIE-19K-028-2655966-00		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Prednisone			S	Oral			Not Reported

Prednisone	S	Oral	Not Reported
Prednisone	S	Oral	Not Reported
Prednisone	S	Oral	Not Reported
Prednisone	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Triamcinolone Hexacetonide	S	Intra-articular	Not Reported
Triamcinolone	S	Intra-articular	Not Reported
Triamcinolone	S		Not Reported
Naproxen	S	Unknown	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Kineret	S	Subcutaneous	Not Reported
Kineret	S		Not Reported
Naproxen Sodium	S	Unknown	Not Reported
Gammagard	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Immune Globulin (Human)	S	Intravenous (not otherwise specified)	Not Reported
Triamcinolone Acetonide	S	Intra-articular	Not Reported
Triamcinolone Acetonide	S		Not Reported
Triamcinolone Acetonide	S		Not Reported
Tocilizumab	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S		Not Reported
Apo-Naproxen	S	Unknown	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Vaccinia Immune Globulin (Immunoglobulin G Human)	S	Unknown	Not Reported
Folic Acid	C		Not Reported

	Triamcinolone Hexacetonide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	16140356	EXPEDITED (15-DAY)		OT	PHHY2019CA070200		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Cosentyx			S	Unknown	Unk		Novartis
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	16403034	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2809805-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Hospitalisation; Infection; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Off Label Use; Pain; Pain In	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Enbrel			S	Unknown	823		Not Reported

Extremity; Peripheral Swelling; Pneumonia; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Enbrel	S	Unknown	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Sulfasalazine	S	Subcutaneous	Not Reported
	Apo Leflunomide	S	Unknown	Not Reported
	Acetaminophen W/Diphenhydramine Hydrochloride	S	Unknown	Not Reported
	Apo-Acetaminophen	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Tylenol	S	Unknown	Not Reported
	Doxycycline Hyclate	S	Unknown	Not Reported
	Tylenol W/Codeine No. 3	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Acetaminophen And Codeine Phosphate	C		Not Reported
	Methotrexate	C	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Hydromorphone Hydrochloride	C	Unknown	Not Reported
	Celebrex	C	Oral	Not Reported
	Leflunomide	C		Not Reported
	Codeine	C		Not Reported
	Celecoxib	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	16408931	EXPEDITED (15-DAY)		HO, OT	PHHY2019CA127221		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Voltaren	S	Unknown	Unk	Novartis
	Voltaren	S			Novartis
	Voltaren	S			Novartis
	Voltaren	S			Novartis
	Diclofenac Potassium	S	Unknown		Novartis
	Diclofenac Potassium	S			Novartis
	Diclofenac Potassium	S			Novartis
	Diclofenac Potassium	S			Novartis
	Diclofenac	S	Unknown	Unk	Novartis
	Diclofenac	S			Novartis
	Diclofenac	S			Novartis
	Diclofenac	S			Novartis
	Acetylsalicylic Acid Sandoz	S	Unknown	325 Mg	Not Reported
	Acetylsalicylic Acid Sandoz	S			Not Reported
	Acetylsalicylic Acid Sandoz	S			Not Reported
	Acetylsalicylic Acid Sandoz	S			Not Reported
	Vitamin C	S	Unknown		Not Reported
	Clopidogrel	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S			Not Reported
	Ibuprofen	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S			Not Reported
	Arava	S			Not Reported
	Arava	S			Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S			Not Reported
	Enbrel	S			Not Reported
	Enbrel	S			Not Reported
	Gold	S	Unknown		Not Reported
	Gold	S			Not Reported
	Gold	S			Not Reported
	Gold	S			Not Reported

Humira	S	Subcutaneous		Not Reported
Humira	S			Not Reported
Humira	S			Not Reported
Humira	S			Not Reported
Motrin	S	Unknown		Not Reported
Motrin	S			Not Reported
Motrin	S			Not Reported
Motrin	S			Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Plaquenil	S			Not Reported
Plaquenil	S			Not Reported
Plaquenil	S			Not Reported
Sulfamethoxazole And Trimethoprim	S	Unknown		Not Reported
Aspirin	S	Oral	Unk	Not Reported
Aspirin	S			Not Reported
Aspirin	S			Not Reported
Aspirin	S			Not Reported
Naprosyn	S	Unknown		Not Reported
Naprosyn	S			Not Reported
Naprosyn	S			Not Reported
Naprosyn	S			Not Reported
Acetylsalicylic Acid W/Clopidogrel	S	Unknown		Not Reported
Apo Sulfatrim	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Oral		Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Sulphamethoxazole	S	Unknown		Not Reported
Apo-Diclofenac	S	Unknown		Not Reported
Sulfatrim	S	Unknown		Not Reported
Tramadol Hcl	C	Unknown		Not Reported
Tramadol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	16762680	EXPEDITED (15-DAY)		OT	DE-DEXPHARM-20190689			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported
	Quensyl			S	Unknown			Not Reported
	Eliquis			S		2.5 Mg Bid		Not Reported
	Roactemra			S				Not Reported
	Spasmolyt			S				Not Reported
	Spasmolyt			S				Not Reported
	Omeprazole			S	Oral	20 Mg Every 12 Hours: In The Morning And In The Evening		Not Reported
	Ramipril			S	Oral	In The Morning And In The Evening		Not Reported
	Volibris			S				Not Reported
	Sildenafil Citrate			S				Not Reported
	Lyrica			S		100 Mg, Tid		Not Reported
	Pregabalin			S		1 Df, 3x/Day (1 - 1- 1)		Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1 - 0 - 1)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17271238	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202001000259			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dry Eye; Dry Mouth; Lower Respiratory Tract Infection	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Salagen			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Vimovo			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Vitamin D3			C		25 Ug		Not Reported
	Methotrexate			C		Unk		Not Reported

	Celebrex	C	Unk	Not Reported
	Arthrotec	C	Unk	Not Reported
	Meloxicam	C	Unk	Not Reported
	Omega 3	C	Unk	Not Reported
	Orthotics	C		Not Reported
	Orthotics	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17488060	NON-EXPEDITED			US-PFIZER INC-2020092938		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Back Disorder; Breast Cyst; Bronchitis; Chest Pain; Condition Aggravated; Dyspnoea; Fibromyalgia; Frustration Tolerance Decreased; Insomnia; Joint Swelling; Malaise; Memory Impairment; Musculoskeletal Stiffness; Nodule; Osteoarthritis; Pain; Product Dose Omission; Respiratory Disorder; Weight Increased	Xeljanz Xr			S	Oral	11 Mg, 1x/Day		Pfizer
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17532940	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA067280			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anaphylactic Shock; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nausea;	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	20 Mg, Unknown		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	520 Mg		Not Reported

Renal Impairment; Synovitis	Methotrexate	S	Unknown	20 Mg, Unknown	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Otezla	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17658870	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202003001936			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17659181	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202003002316			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Irbesartan			C		Unk		Not Reported
	Lercanidipine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17659505	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030160		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Prescribed Underdose	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported

Enbrel	S	Subcutaneous	40 Milligram, Qwk		Not Reported
Humira	S	Subcutaneous	40 Milligram		Not Reported
Humira	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	40 Milligram, Qwk		Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Endocervical			Not Reported
Methotrexate	S	Subcutaneous	Unk		Not Reported
Methotrexate	S	Oral			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17659894	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030087		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Loss Of Consciousness; Mobility Decreased; Nausea; Pulmonary Fibrosis; Rheumatoid Factor Positive; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qh		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram		Not Reported

Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Risedronate Sodium	S	Unknown	35 Milligram, Qwk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 Gram		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Xeljanz	S	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17660024	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020145583		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Incorrect Route Of Product Administration; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Celebrex			S	Unknown			Pfizer
	Enbrel			S	Subcutaneous			Pfizer
	Methotrexate Sodium			S	Unknown			Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	500 Mg, Unk		Pfizer
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Mg, 1 Every 1 Day		Not Reported
	Arava			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisone			S	Endocervical			Not Reported
	Risedronate Sodium			S	Unknown	5 Mg, Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Cyclobenzaprine			C	Unknown	10 Mg, Unk		Not Reported
	Desoximetasone			C	Unknown	5 Mg, 1x/Day		Not Reported

	Desoximetasone		C	Unknown	5 Mg, Unk	Not Reported
	Leflunomide		C	Unknown		Not Reported
	Prednisone Acetate		C	Unknown	5 Mg,1 Every 1 Day	Not Reported
	Tylenol [Paracetamol]		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17660039	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020145608			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Blister; Drug Ineffective; Feeling Abnormal; Gastrointestinal Disorder; Hepatic Enzyme Abnormal; Inappropriate Schedule Of Product Administration; Mouth Haemorrhage; Mouth Ulceration; Musculoskeletal Discomfort; Nausea; Psoriatic Arthropathy; Pyrexia; Synovitis	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	12.5 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Lipitor			S	Oral			Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Arthrotec			S				Pfizer
	Cimzia			S		Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Dovobet			C	Topical			Not Reported
	Flovent			C				Not Reported
	Folic Acid			C	Oral			Not Reported
	Multi Vitamin & Mineral			C	Oral			Not Reported
	Omeprazole			C	Oral			Not Reported
	Ventolin [Salbutamol]			C				Not Reported
	Vitamin D2			C	Oral	1000 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17660080	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020147592			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deformity; Movement Disorder; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Methotrexate Sodium			S	Unknown			Pfizer
	Myochrysine			S	Unknown			Not Reported
	Aralen [Chloroquine Sulfate]			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17660089	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020147560			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Skin Lesion; Treatment Failure; Uveitis	Methotrexate Sodium			S	Unknown			Pfizer
	Aralen [Chloroquine Sulfate]			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17660093	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020146051			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Antinuclear Antibody Positive; Arthralgia; Arthritis; Blister; Dry Mouth; Headache; Hypersensitivity Vasculitis; Hypoaesthesia; Joint Swelling; Leukopenia; Lip Swelling; Lymphadenopathy; Menorrhagia; Musculoskeletal Stiffness; Myalgia; Nausea; Parotid Gland Enlargement; Peripheral Swelling; Rheumatoid Arthritis; Sjogren'S Syndrome; Systemic Lupus Erythematosus; Vasculitis	Methotrexate Sodium	S	Oral	Unk	Pfizer
	Methotrexate Sodium	S	Intravenous (not otherwise specified)	Unk	Pfizer
	Celebrex	S	Unknown	Unk	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Rituximab	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Belimumab	S	Unknown	Unk	Not Reported
	Breo Ellipta	S	Respiratory (inhalation)	Unk	Not Reported
	Colchicine	S	Unknown		Not Reported
	Dexilant	S	Oral	60 Mg, 1x/Day	Not Reported
	Estrogel	S	Topical	Unk Unk, 1x/Day	Not Reported
	Meloxicam	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Mg, 2x/Day	Not Reported
	Prednisone	S	Unknown	50 Mg, Unk	Not Reported
	Ventolin Hfa	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17660569	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020147922			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Musculoskeletal Stiffness; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Skin Lesion; Uveitis	Methotrexate Sodium			S		Unk		Pfizer
	Remicade			S		Unk		Not Reported
	Aralen Hydrochloride			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Myochrysine			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17661320	DIRECT	Y	OT			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Electrocardiogram Qt Prolonged; Transaminases Increased	Hydroxychloroquine			S	Oral			Not Reported
	Lopinavir/Ritonavir			S	Oral			Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17661328	DIRECT	Y	OT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Hydroxychloroquine			S	Oral			Not Reported
	Lopinavir/Ritonavir			S				Not Reported
	Atorvastatin 80mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17661548	EXPEDITED (15-DAY)		OT	NVSC2020CA096823		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Rituximab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate Disodium			S	Subcutaneous	25 Mg, Qw		Not Reported
	Methotrexate Disodium			S	Oral	20 Mg, Qw		Not Reported
	Ciclosporin Sandoz			S	Subcutaneous	Unk		Novartis
	Adalimumab			S	Subcutaneous	40 Mg		Not Reported
	Actemra			S	Intravenous (not	Unk		Not Reported

		otherwise specified)		
Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
Apo-Hydroxyquine	S	Oral	Unk	Not Reported
Apo-Leflunomide	S	Oral	Unk, Qd	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Q2w	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Q2w	Not Reported
Hydroxychloroquine	S	Oral	20 Mg	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	20 Mg, Bid	Not Reported
Hydroxychloroquine Sulfate	S			Not Reported
Orencia	S	Unknown	75 Mg, Qmo	Not Reported
Orencia	S	Subcutaneous	125 Mg	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Oral	500 Mg, Qd	Not Reported
Sulfasalazine	S			Not Reported
Xeljanz	S	Oral	5 Mg, Bid	Not Reported
Avara	C	Oral	20 Mg, Qd	Not Reported
Rituxan	C	Unknown	500 Mg, Qd	Not Reported
Cimzia	C	Subcutaneous	200 Mg, Q2w	Not Reported
Risedronate	C	Oral	25 Mg, Qw	Not Reported
Risedronate	C	Oral	30 Mg, Qw	Not Reported
Plaquenil	C	Oral	200 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17661837	EXPEDITED (15-DAY)		OT	NVSC2020CA097860		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Treatment Failure	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral	20 Mg	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Neoral	S	Oral	Unk	Novartis
	Neoral	S	Subcutaneous	Unk	Novartis
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Ciclosporin Sandoz	S	Unknown		Novartis
	Sulfasalazine	S	Oral		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Every 1 Week	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous	125 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17661903	DIRECT	Y	LT			47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged	Plaquenil			S				Not Reported
	Azithromycin Tablet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662053	EXPEDITED (15-DAY)		LT	FR-TEVA-2020-FR-1223033		54 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Azithromycine Anhydre			S	Oral	Unknown Dosage		Not Reported
	Plaquenil			S	Oral	800 Mg		Not Reported
	Augmentin			C	Oral	Unknown Dosage		Not Reported
	Hypnovel			C				Not Reported
	Sufentanil			C				Not Reported
	Etomidate			C				Not Reported
	Tracrium			C				Not Reported
	Esmeron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662107	EXPEDITED (15-DAY)		OT	NVSC2020CA097244		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported

Hydroxychloroquine Sulfate	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk		Not Reported
Orencia	S	Subcutaneous	125 Mg		Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg		Not Reported
Rituximab	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Oral			Not Reported
Xeljanz	C	Oral	5 Mg, Qd (2 Every 1 Days)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662141	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003002380			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Hydroxychloroquine			S	Oral	400 Mg, Qd (Fiim-Coated Tablet)		Concordia
	Enoxaparin			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662227	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003002617			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Lupus Erythematosus; Stress	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662417	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003003386			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia

	Azithromycin	S	Unknown	Unk	Not Reported
	Zinc Salt Nos	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662684	EXPEDITED (15-DAY)		OT	NVSC2020US098481			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	(1.2-8.3) Mg/Kg		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662798	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1222453		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomyopathy	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663000	EXPEDITED (15-DAY)		OT	NVSC2020CA098112			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Dactylitis; Drug Ineffective; Enthesopathy; Inflammation; Joint Stiffness; Psoriasis; Psoriatic Arthropathy; Tenosynovitis; Vertigo	Cosentyx			S	Unknown	300 Mg, Qmo		Novartis
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Prednisone			C	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663200	EXPEDITED (15-DAY)		HO, OT	FR-ADVANZ PHARMA-202003002813			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatitis; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil		S	Unknown	Unk (Film-Coated Tablet)	Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663224	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003002823			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Nivaquine			S	Unknown	1 Dosage Form, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663282	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202004002844			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Fall; Femur Fracture; Hypoacusis; Intentional Product Use Issue; Product Dose Omission; Unevaluable Event	Hydroxychloroquine			S	Unknown	2cp/Day, Qd		Concordia
	Hydroxychloroquine			S		1cp/Day For 15		Concordia
	Cardensiel			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663302	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004002921			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663508	EXPEDITED (15-DAY)		DE	FR-ABBVIE-20K-056-3361937-00			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Death	Kaletra 200/50		S	Oral	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663522	EXPEDITED (15-DAY)		DE	FR-ABBVIE-20K-056-3362044-00			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Kaletra 200/50			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663539	EXPEDITED (15-DAY)		DE	FR-ABBVIE-20K-056-3362011-00			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Kaletra 200/50			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17665337	DIRECT	Y	OT			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Transaminases Increased	Hydroxychloroquine Oral Tablet			S	Oral			Not Reported
	Lopinavir/Ritonavir			S	Oral			Not Reported
	Atorvastatin 40mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17665521	DIRECT	Y	DE, HO			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Test Positive	Hydroxychloroquine 200mg Po			S	Oral			Actavis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	11925949	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-ABBVIE-15K-028-1444053-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Arthroplasty; Joint Swelling; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Myocardial Infarction; Near Death Experience; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Subcutaneous			Not Reported
	Gold			S				Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S				Not Reported

Plaquenil	S	Oral		Not Reported
Plaquenil	S			Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Apo-Hydroxyquine	S			Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Sodium Aurothiomalate	S			Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S			Not Reported
Arava	S	Unknown		Not Reported
Arava	S			Not Reported
Medical Marijuana	S	Unknown		Not Reported
Minocycline	S	Unknown		Not Reported
Oxycodone Hydrochloride	S	Unknown		Not Reported
Xeljanz	S	Oral		Not Reported
Minocycline Hydrochloride	S	Unknown		Not Reported
Anakinra	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S			Not Reported
Oxycodone	S	Unknown		Not Reported
Cannabis Sativa	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S			Not Reported
Kineret	C			Not Reported
Rituximab	C			Not Reported
Kineret	C	Unknown		Not Reported
Lyrica	C	Unknown		Not Reported
Ilaris	C	Subcutaneous	Single-Use Vial	Not Reported
Rituximab W/Urelumab	C	Unknown		Not Reported
Anakinra	C	Unknown		Not Reported
Urelumab	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	14144042	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP020346		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Spinal Stenosis; Synovitis	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Qd		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Qd		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Once Every Four Weeks		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Unk 1 Every 4 Months		Not Reported
	Orencia			S	Unknown	500 Unk, Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Q.Wk.		Not Reported

Methotrexate	S	Oral	Unk		Not Reported
Methotrexate	S	Subcutaneous	12.5 Mg, Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	5 Mg, Bid		Not Reported
Xeljanz	C	Unknown	Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	14243063	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021705			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Exposure During Pregnancy; Fatigue; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Winpred			S	Oral	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg, Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported

Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Pseudoephedrine Hcl	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Plaquenil /00072602/	S	Unknown	Unk		Not Reported
Desoximetasone	S	Oral	Unk		Not Reported
Reactine /00884302/	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk		Not Reported
Methotrexate	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	14404773	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP005233			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown	Unk		Apotex
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Methotrexate	S	Unknown	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Plaquenil /00072602/	S	Unknown	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Reactine /00884302/	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	14558788	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2262991-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Gold			S	Other			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	15132896	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018014806			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Pantoprazole			S	Transplacental	40 Milligram, Qd, 40 [Mg/D]; 0-13.6 Gestational Week		Macleods
	Pantoprazole			S	Transplacental	Unk		Macleods
	Aspirin			S	Transplacental	100 Milligram, Qd, From Gestational Week 0-14		Not Reported
	Aspirin			S	Transplacental	Unk		Not Reported
	Prednisolone			S	Transplacental	10 Milligram, Bid, Tablet, From Gestational Week 0-14		Not Reported
	Simvastatin			S	Transplacental	Unk		Not Reported
	Simvastatin			S	Transplacental	Unk, Tablet, From Gestational Week 0-14		Not Reported
	Tacrolimus			S	Transplacental	6 Milligram, Qd, From Gestational Week 0-14		Not Reported
	Tacrolimus			S	Transplacental	Unk, 1 Trimester		Not Reported
	Tacrolimus			S	Transplacental	Unk		Not Reported
	Heparins, Low-Molecular-Mass			S	Transplacental	Unk		Not Reported
	Heparins, Low-Molecular-Mass			S	Transplacental	Unk		Not Reported
	Salbutamol Sulfate			S	Transplacental	Unk Unk, Qd, From Gestational Week 0-14		Not Reported
	Salbutamol Sulfate			S	Transplacental	Unk		Not Reported
	Metamizole Sodium			S	Transplacental	Unk		Not Reported
	Metamizole Sodium			S	Transplacental	Unk,From Gestational Week 0-14		Not Reported

Nicotine	S	Transplacental	Unk	Not Reported
Nicotine	S	Transplacental	Unk, From Gestational Week 0-14	Not Reported
Ramipril	S	Transplacental	20 Milligram, From Gestational Week 0-13+6 Weeks) Maternal Dose 20 Mg	Not Reported
Hydroxychloroquine	S	Transplacental	400 Milligram, Qd, From Gestational Week 0-14	Not Reported
Aliskiren	S	Transplacental	300 Milligram, Qd, 300 [Mg/D]; 0-4.6 Gestational Week	Not Reported
Aliskiren	S	Transplacental	Unk	Not Reported
Rivaroxaban	S	Transplacental	Unk	Not Reported
Rivaroxaban	S	Transplacental	Unk	Not Reported
Ezetimibe	S	Transplacental	Unk, Tablet, From Gestational Week 0-14	Not Reported
Ezetimibe	S	Transplacental	Unk	Not Reported
Torasemide	S	Transplacental	100 Mg Qd From Gestational Week 0-14	Not Reported
Xarelto	S	Transplacental	Unk, Film Coated Tablet,From Gestational Week 0-5	Not Reported
Clexane	S	Transplacental	200 Milligram, Qd, 2 X 100	Not Reported
Dalteparin Sodium	S	Transplacental	Unk	Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional, Trimester: Preconceptional	Not Reported
Rasilez	S	Unknown		Not Reported
Enoxaparin Sodium	S	Transplacental	Unk, From Gestational Week 0-14	Not Reported
Acetylsalicylic Acid	S	Transplacental	100 Milligram, Qd	Not Reported
Novaminsulfon	S	Transplacental	Unk, Trimester: First;	Not Reported

				Probably Only In Hospital In Week 5	
	Cytotec	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
	Mifegyne	C	Transplacental	Unk, 13.6 Gestational Week	Not Reported
	Cyclophosphamide	C	Transplacental	Unk, 3000 [Mg Cumulative]; Preconceptional	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	15337014	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019548		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis;	Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk, Therapy Duration: 59		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Meloxicam			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	160 Mg, Q.Wk.		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Mobicox			S	Unknown	Unk		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			C	Unknown	Unk		Not Reported
	Plaquenil /00072602/			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Depo-Medrol			C	Intra-articular	80 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	15622524	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557260-00		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Off Label Use	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Diclofenac			C				Not Reported
	Desoximetasone			C	Oral			Not Reported
	Xeljanz			C	Subcutaneous			Not Reported
	Zostavax			C	Subcutaneous			Not Reported
	Methotrexate			C				Not Reported
	Voltaren			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	15629606	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-		51 YR	Female	CAN

2555539-00

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Contraindicated Product Administered; Cough; Cough; Diarrhoea; Diarrhoea; Drug Ineffective; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Headache; Infection; Intentional Product Use Issue; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Prednisone			C				Not Reported
	Prevacid			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	15670302	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2571378-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Humira			S	Subcutaneous			Not Reported
	Mefenamic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1 Dosage Forms		Not Reported
	Enbrel			S	Subcutaneous	1 Dosage Forms		Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S				Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

			otherwise specified)	
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Tylenol	C	Unknown	Not Reported
	Advil	C		Not Reported
	Dequalinium Chloride	C	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	15806693	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2618205-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Myochrysine	S	Parenteral	Foa-Solution Inramuscular	Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Foa-Solution Intravenous	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Codeine	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Alendronate	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

	Etanercept	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Alendronic Acid	S	Unknown	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Codeine Sulfate	S	Unknown	Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C		Not Reported
	Ciclosporin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	16079861	EXPEDITED (15-DAY)		DS, HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-06082		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Fatigue;	Infliximab			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Etanercept			S	Unknown	Unknown		Not Reported
	Etanercept			S				Not Reported
	Apo-Ibuprofen			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral	Unknown		Not Reported
	Apremilast			S	Oral			Not Reported
	Apremilast			S	Unknown	Unknown		Not Reported
	Apremilast			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous	Unknown		Not Reported
	Ciclosporin			S	Oral	Unknown		Not Reported
	Ciclosporin			S	Subcutaneous	Unknown		Not Reported

General Physical Health Deterioration; Granuloma Skin; Headache; Hepatic Enzyme Increased; Hypercalcaemia; Hypersensitivity; Infection; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer	Cimzia	S	Subcutaneous	Unknown (Solution), Single Use Pre-Filled Syringe	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous	Unknown (Solution)	Not Reported
	Golimumab	S	Subcutaneous	Unknown	Not Reported
	Motrin	S	Oral		Not Reported
	Motrin	S	Unknown		Not Reported
	Orencia	S	Subcutaneous	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Otezla	S	Oral		Not Reported
	Otezla	S	Unknown	Unknown	Not Reported
	Otezla	S			Not Reported
	Simponi	S	Subcutaneous	Unknown (Solution)	Not Reported
	Stelara	S	Subcutaneous	Unknown (Solution)	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Ustekinumab	S	Subcutaneous	Unknown	Not Reported
	Ibuprofen	S	Oral		Not Reported
	Ibuprofen	S	Oral		Not Reported
	Ibuprofen	S	Unknown		Not Reported
	Leflunomide	S	Oral	Unknown	Not Reported
	Sulfamethoxazole	S	Oral		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Apo-Cyclosporine	S	Oral	Unknown	Not Reported
	Codeine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported

Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Tocilizumab	S	Unknown		Not Reported
Colchicine	C	Oral		Not Reported
Febuxostat	C	Unknown		Not Reported
Febuxostat	C	Unknown		Not Reported
Folic Acid	C	Unknown	Unknown	Not Reported
Methotrexate	C	Unknown		Not Reported
Methotrexate	C	Unknown		Not Reported
Methotrexate	C	Oral	Unknown	Not Reported
Methotrexate	C	Unknown	Unknown	Not Reported
Mogadon	C	Unknown		Not Reported
Nitrazepam	C	Oral		Not Reported
Oxycodone Hydrochloride	C	Unknown		Not Reported
Oxycodone Hydrochloride	C	Unknown		Not Reported
Oxyneo	C	Unknown		Not Reported
Oxyneo	C	Unknown	(Extended Release)	Not Reported
Uloric	C	Oral		Not Reported
Benadryl	C	Unknown	Unknown	Not Reported
Dexilant	C	Unknown	Unknown (Delayed Release)	Not Reported
Dexilant	C	Unknown	Unknown, Prolonged Release	Not Reported
Gravol	C	Unknown	Unknown	Not Reported
Oxycodone	C	Unknown		Not Reported
Oxycodone	C	Unknown		Not Reported
Acide Folique	C	Unknown	Unknown	Not Reported
Methotrexate Sodium	C	Oral		Not Reported
Prednisone	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	16589246	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2851920-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Desoximetasone			C				Not Reported
	Gold			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	16954774	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2972637-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Inflammation; Local Reaction; Musculoskeletal Pain; Nausea; Neck Pain; Pain In Extremity; Rash; Syncope; Vomiting	Humira			S	Subcutaneous			Not Reported
	Plantago Afra			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Morphine	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Aclasta	S	Intravenous (not otherwise specified)	Not Reported
	Morphine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Asa	C	Unknown	Not Reported
	Hydrochlorothiazide	C		Not Reported
	Ergocalciferol	C		Not Reported
	Folic Acid	C		Not Reported
	Cannabis Sativa	C		Not Reported
	Tums	C		Not Reported
	Lipitor	C		Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Calcium Carbonate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17223484	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3215049-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Bupropion	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Simponi	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17543919	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA072124		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk Unk, Bid		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unknown		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unknown		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	5 Mg, Bid		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40.0 Mg, Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unknown		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Endocervical	400 Mg	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone Acetate	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5.0 Mg, Bid	Not Reported
Xeljanz	S	Oral	5.0 Mg, Bid	Not Reported
Acetaminophen And Codeine	C	Unknown	Unk	Not Reported
Celebrex	C	Unknown	2 Df, Qd	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Folic Acid	C	Subcutaneous	Unk	Not Reported
Insulin	C	Oral	Unk (Drops)	Not Reported
Metformin	C	Unknown	2 Df, Bid	Not Reported
Metformin	C	Unknown	1 Unk	Not Reported
Plaquenil	C	Unknown		Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17552068	EXPEDITED (15-DAY)		HO, OT	JP-GLAXOSMITHKLINE-JP2020JPN044468		40 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Infection	Belimumab			S	Intravenous drip	Unk		Glaxosmithkline

Belimumab	S	Intravenous drip	10 Mg/Kg, Once In Every Four Weeks	Glaxosmithkline
Belimumab	S	Intravenous drip	10 Mg/Kg, Once In Every Four Weeks	Glaxosmithkline
Prednisolone	S	Oral	Unk	Glaxosmithkline
Prednisolone	S	Oral	10 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	9 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	8 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	7 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	6 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	7 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	8 Mg, 1d	Glaxosmithkline
Tacrolimus	S	Unknown	Unk	Glaxosmithkline
Imuran	S	Unknown	Unk	Glaxosmithkline
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Bonoteo	C		Unk	Not Reported
Lansoprazole	C		Unk	Not Reported
Bayaspirin	C		Unk	Not Reported
Rebamipide	C		Unk	Not Reported
Baktar	C		Unk	Not Reported
Colonel	C		Unk	Not Reported
Loxofen (Loxoprofen Sodium)	C		Unk	Not Reported
Amerge	C		Unk	Not Reported
Sumilu Stick	C		Unk	Not Reported
Celecox	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17572131	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332786		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diverticulitis; Therapeutic Product Effect Incomplete	Simponi	S	Subcutaneous	Janssen
	Simponi	S		Janssen
	Actemra	S	Unknown	Not Reported
	Apo-Prednisone	S		Not Reported
	Arava	S		Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Plaquenil /00072602/	S		Not Reported
	Sulfasalazine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17594562	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332781		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Treatment Failure; White Blood Cell Count Decreased	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17605651	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332787		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Rash; Syncope; Urticaria	Simponi	S	Subcutaneous	Janssen
	Simponi	S		Janssen
	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Actemra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prevacid	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17605666	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332776		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Rheumatoid Arthritis; Sleep Disorder	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Stelara			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Minocycline Hydrochloride	S	Unknown	Not Reported
Minocycline Hydrochloride	S		Not Reported
Myochrysine	S	Intramuscular	Not Reported
Otezla	S	Unknown	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Salazopyrin	S	Unknown	Not Reported
Sirukumab	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Methotrexate	C	Unknown	Not Reported
Orencia	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17636246	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-PBT-000165			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Truncus Arteriosus Persistent; Ventricular Septal Defect	Tacrolimus			S	Transplacental			Panacea Biotec
	Tacrolimus			S	Transplacental			Panacea Biotec
	Tacrolimus			S	Transplacental			Panacea Biotec
	Rivaroxaban			S	Transplacental			Not Reported
	Rivaroxaban			S	Transplacental			Not Reported
	Nicotine			S	Transplacental			Not Reported
	Simvastatin			S	Transplacental			Not Reported
	Acetylsalicylic Acid			S	Transplacental			Not Reported
	Acetylsalicylic Acid			S	Transplacental			Not Reported
	Pantoprazole			S	Transplacental			Not Reported
	Pantoprazole			S	Transplacental			Not Reported

	Torasemide	S	Transplacental	Not Reported
	Ramipril	S	Transplacental	Not Reported
	Ramipril	S	Transplacental	Not Reported
	Aliskiren	S	Transplacental	Not Reported
	Prednisolone	S	Transplacental	Not Reported
	Prednisolone	S	Transplacental	Not Reported
	Dipyrone	S	Transplacental	Not Reported
	Dipyrone	S	Transplacental	Not Reported
	Hydroxychloroquine Sulfate	S	Transplacental	Not Reported
	Heparin	S	Transplacental	Not Reported
	Heparin	S	Transplacental	Not Reported
	Salbutamol Sulfate	S	Transplacental	Not Reported
	Salbutamol Sulfate	S	Transplacental	Not Reported
	Ezetimibe	S	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17663632	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018207		52 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day (Dia)		Aurobindo
	Azithromycin			S				Aurobindo
	Paracetamol			S	Oral	1 Gram, 3 Times A Day (1gr Cada 8 Horas)		Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day (Dia)		Not Reported
	Dolquine			S	Oral	400 Milligram, Once A Day (Dia)		Not Reported
	Dolquine			S				Not Reported
	Simvastatina Alter			S	Oral	0-0-1		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17663750	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201706-003792			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Apoleflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17663778	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020147529		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Enbrel			S	Subcutaneous	40 Mg, Weekly		Pfizer

Methotrexate Sodium	S	Oral	Unk		Pfizer
Methotrexate Sodium	S	Subcutaneous	Unk		Pfizer
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Monthly		Not Reported
Apo-Azathioprine	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	40 Mg, Unk		Not Reported
Humira	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	40 Mg, Weekly		Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Endocervical	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	0.75 Mg, Monthly		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17663950	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021948		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Apremilast			S	Unknown	30 Mg, Bid		Not Reported
	Methotrexate Sodium			S	Oral	30 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	30 Mg, Bid		Not Reported
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17664171	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deformity; Movement Disorder; Polyarthritis; Product Use In Unapproved Indication; Skin Lesion; Treatment Failure; Uveitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17664175	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1694			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Red Blood Cell Sedimentation Rate Increased; Renal Impairment	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17664213	EXPEDITED (15-DAY)		DE	ES-ABBVIE-20K-144-3361763-00		95 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Kaletra 200/50			S	Oral			Not Reported

Quetiapina	S	Oral	Not Reported
Levofloxacino	S	Intravenous (not otherwise specified)	Not Reported
Hidroxicloroquina Sulfato	S	Oral	Not Reported
Risperidona	S	Oral	Not Reported
Losartan	C	Oral	Not Reported
Clindamicina Hidrocloruro	C	Intravenous (not otherwise specified)	Not Reported
Lorazepam	C	Oral	Not Reported
Furosemida	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17664281	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1710			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Polyarthritis; Product Use In Unapproved Indication; Skin Lesion; Treatment Failure; Uveitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17664285	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1705			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuropathy Peripheral	Methotrexate (Trade Name			S	Unknown			Not Reported

	Unknown)			
	Celebrex	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Codeine Phosphate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Plaquenil S	S	Unknown	Not Reported
	Azathioprine Sodium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17664555	EXPEDITED (15-DAY)		OT	HK-ACCORD-178663		67 YR	Female	HKG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Tuberculosis	Methotrexate			S				Accord
	Prednisolone			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Tocilizumab			S				Not Reported
	Tofacitinib			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17665208	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020145791		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Fibromyalgia; Lymphoedema; Obesity; Pneumocystis Jirovecii Pneumonia; Pulmonary Embolism	Xeljanz			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

Calcium/Vitamin D3	C	Unk		Not Reported
Hydrocortisone	C	Unk Unk, 2x/Day		Not Reported
Pantoloc [Pantoprazole]	C	Unk		Not Reported
Prednisone	C	20 Mg, 1x/Day		Not Reported
Tylenol Arthritis Pain	C	2 Df, 2x/Day		Not Reported
Xarelto	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17665668	NON-EXPEDITED		HO, OT	NVSC2020US099010		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Chest Pain; Cough; Decreased Appetite; Dyspnoea; Hepatitis Viral; Nausea; Pyrexia	Prednisone			S	Unknown	5 Mg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Metronidazole			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17665946	EXPEDITED (15-DAY)		DE, HO, OT	SK-HORIZON-PRE-0109-2020		57 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Bulbar Palsy; Cardiac Arrest; Dizziness; Hypotension; Intentional Product Use Issue; Jc Virus Infection; Mental Impairment; Off Label Use; Pneumonia; Progressive Multifocal Leukoencephalopathy; Respiratory Failure; Speech Disorder; Tremor	Prednisone			S				Not Reported
	Azathioprine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Cyclosporine A			S				Not Reported
	Methotrexate			S				Not Reported
	Belimumab			S				Not Reported
	Cyclophosphamide			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17666426	EXPEDITED (15-DAY)		OT	NVSC2020PT099374		48 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17667117	EXPEDITED (15-DAY)		OT	NVSC2020CA098733			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Bone Erosion; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Exostosis; Foot Deformity; Hepatic Cirrhosis; Joint Dislocation; Joint Stiffness; Off Label Use; Osteoarthritis; Osteoporosis; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sirukumab			S	Unknown	Unk		Not Reported

Stelara	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Xeljanz	S	Oral	5 Mg, Bid		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Wellbutrin	C	Unknown			Not Reported
Dilaudid	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17667548	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2375555-00		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Certolizumab			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported
	Leucovorin Calcium			C				Not Reported
	Codeine			C				Not Reported
	Ibuprofen			C				Not Reported
	Dilaudid			C				Not Reported
	Plaquenil			C				Not Reported
	Acetaminophen			C				Not Reported
	Ventolin Hfa			C				Not Reported
	Nexium Dr			C				Not Reported
	Advair Diskus			C				Not Reported
	Allopurinol			C				Not Reported
	Cyclobenzaprine Hcl			C				Not Reported
	Atrovent Hfa			C				Not Reported
	Hydromorphone Hcl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17667774	EXPEDITED (15-DAY)		OT	NVSC2020CA098830			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nausea; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting; White Blood Cell Count Decreased	Cosentyx			S	Unknown	150 Mg, Unknown		Novartis
	Methotrexate			S	Oral	15 Mg, Unknown		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unknown		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Unknown		Not Reported
	Otezla			S	Oral	30 Mg, Bid		Not Reported
	Sulfasalazine			C	Unknown	1 G, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17667856	EXPEDITED (15-DAY)		OT	NVSC2020CA098863		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Cosentyx			S	Unknown	Unk		Novartis
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Erythromycin			C	Unknown	Unk		Not Reported
	Morphine			C	Topical	Unk		Not Reported
	Methotrexate			C	Oral	1 Df, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17668265	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-017705			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Nightmare; Product Use In Unapproved Indication; Psychomotor Hyperactivity	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17668362	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3362555-00			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Musculoskeletal Stiffness; Polyarthritis; Skin Lesion; Uveitis	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17668434	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030217		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation;	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Apo-Leflunomide			S	Oral	10 Milligram		Not Reported
	Cefazolin			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Milligram, 1 Every 2		Not Reported

Infection; Rash; Rheumatoid Arthritis; Urticaria				Weeks, Duration 1 Days And 15 Days	
	Certolizumab Pegol	S	Subcutaneous	200 Milligram, 1 Every 2 Weeks, Duration 2.0 Years	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, 2 Every 1 Days	Not Reported
	Leflunomide	S	Oral	10 Milligram, Duration 2 Months	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, 1 Every 1 Week, Duration 2 Months	Not Reported
	Plaquenil S	S	Unknown	200 Milligram, 2 Every 1 Days	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Amlodipine	C	Unknown	Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Tofacitinib Citrate	C	Unknown	5 Milligram, 2 Every 1 Days	Not Reported
	Viread	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17668438	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-017975		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance; Product Use In Unapproved Indication	Clindamycin			S	Unknown	300 Milligram, Two Times A Day		Aurobindo
	Rifampin			S	Unknown	600 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Two Times A Day (Monday Through Friday)		Not Reported
	Clobetasol			S	Unknown	Unk Unk, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17669671	DIRECT					54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angiopathy; Anxiety; Burning Sensation; Fatigue; Muscle Spasms; Nervous System Disorder; Nonspecific Reaction; Pain Of Skin; Pruritus	Hydroxychloroquine Sulfate Plaquenil			S	Oral	Quantity:1 Tablet(S);	4 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	8792714	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-009507513-1209DEU004039			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular	Simvastatin			S	Transplacental	Unk		Merck
	Simvastatin			S	Transplacental	From Gestational Week 0-14		Merck
	Viemm 10 Mg Tabletten			S	Transplacental	From Gestational Week 0-14		Merck
	Aspirin			S	Transplacental	From Gestational Week 0-14		Not Reported
	Pantoprazole			S	Transplacental	40 [Mg/D]; 0-13.6		Not Reported

Septal Defect					
				Gestational Week	
	Prednisolone	S	Transplacental	From Gestational Week 0-14	Not Reported
	Enoxaparin Sodium	S	Transplacental	From Gestational Week 0-14	Not Reported
	Albuterol	S	Transplacental	From Gestational Week 0-14	Not Reported
	Torsemide	S	Transplacental	From Gestational Week 0-14	Not Reported
	Novaminsulfon	S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5	Not Reported
	Aliskiren	S	Transplacental	300 [Mg/D]; 0-4.6 Gestational Week	Not Reported
	Dipyrone	S	Transplacental	From Gestational Week 0-14	Not Reported
	Ramipril	S	Transplacental	20 Mg Unk From Gestational Week 0-113+6	Not Reported
	Xarelto	S	Transplacental	From Gestational Week 0-5	Not Reported
	Nicotine	S	Transplacental	From Gestational Week 0-14	Not Reported
	Dalteparin Sodium	S	Transplacental	Unk	Not Reported
	Heparin	S	Transplacental	Unk	Not Reported
	Clexane (Enoxaparin Sodium)	S	Transplacental	200 Mg/D (2x100)	Not Reported
	Hydroxychloroquine Sulfate	S	Transplacental	From Gestational Week 0-14	Not Reported
	Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported
	Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported
	Tacrolimus	S	Transplacental	From Gestational Week 0-	Not Reported

				14	
	Cytotec	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
	Cyclophosphamide	C	Transplacental	3000 [Mg Cumulative]; Preconceptional	Not Reported
	Mifegyne	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	13059562	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015791		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Back Disorder; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Knee Arthroplasty; Mouth Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Spinal Stenosis; Synovitis; Vasculitic Rash	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Qd		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.,		Not Reported
	Humira			S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Humira			S	Unknown	40 Mg, Cyclical		Not Reported

Humira	S	Subcutaneous	40 Mg, Q.O.Wk.,	Not Reported
Humira	S	Subcutaneous	40 Mg, Cyclical	Not Reported
Methotrexate	S	Oral	20 Mg, Qd	Not Reported
Methotrexate	S	Unknown	12.5 Mg, Unk	Not Reported
Methotrexate	S	Unknown	20 Mg, Q.Wk.	Not Reported
Methotrexate	S	Oral	20 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	20 Mg, Q.O.Wk.	Not Reported
Methotrexate	S	Unknown	12.5 Mg, Q.O.Wk.	Not Reported
Orencia	S	Intravenous (not otherwise specified)	500 Mg, Unk, Once Every 4 Weeks	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	500 Mg, Cyclical	Not Reported
Orencia	S	Intravenous (not otherwise specified)	500 Mg, Cyclical	Not Reported
Kineret	S	Subcutaneous	100 Mg, Qd	Not Reported
Methotrexate Sodium	S	Oral	12.5 Mg, Unk	Not Reported
Methotrexate	C	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	12.5 Mg, Unk	Not Reported
Xeljanz	C	Unknown	5 Mg, Bid	Not Reported
Xeljanz	C	Unknown	5 Mg, Unk	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	13059788	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP015748		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Joint Arthroplasty; Joint Swelling; Knee	Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex

Arthroplasty; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Ilaris	C	Unknown		Not Reported
	Plaquenil /00072602/	C	Unknown	Unk	Not Reported
	Rituximab	C			Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Anakinra	C	Unknown	Unk	Not Reported
	Hydroxychloroquine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	14235439	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021912			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Rheumatoid Arthritis; Treatment Failure; Vomiting	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Abatacept			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Morphine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	15391128	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-955090		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pruritus; Rash Maculo-Papular	Repaglinide			S	Oral			Actavis
	Perindopril			S	Oral			Not Reported
	Perindopril			S	Unknown			Not Reported
	Plaquenil			S	Oral	200 Mg/ Day		Not Reported
	Cortancyl			S	Oral	20 Milligram Daily; 10-20µg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	15625329	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2558387-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Tuberculin Test Positive	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Duration:365.0		Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Prednisone	C	Endocervical	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	15760613	NON-EXPEDITED			US-PFIZER INC-2018522861		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Heparin Sodium			S		Unk		Pfizer
	Lisinopril			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Duloxetine			S	Oral	100 Mg, Daily		Not Reported
	Insulin			C		Unk		Not Reported
	Januvia			C		Unk		Not Reported
	Metformin			C		Unk		Not Reported
	Losartan/Hctz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	15819449	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-DRREDDYS-GER/GER/19/0106738			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature	Pantoprazole			S	Transplacental	40 [Mg/D]; 0-13.6 Gestational Week		Not Reported
	Ezetimibe			S	Transplacental			Not Reported
	Ezetimibe			S	Transplacental	From Gestational Week 0-14		Not Reported
	Ramipril			S	Transplacental	20 Mg Unk From Gestational Week 0-113+6		Not Reported

Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Simvastatin	S	Transplacental	From Gestational Week 0-14	Not Reported
	Torasemide	S	Transplacental	From Gestational Week 0-14	Not Reported
	Tacrolimus	S	Transplacental	From Gestational Week 0-14	Not Reported
	Salbutamol	S	Transplacental	From Gestational Week 0-14	Not Reported
	Hydroxychloroquine	S	Transplacental	From Gestational Week 0-14	Not Reported
	Xarelto	S	Transplacental	From Gestational Week 0-5 082(Film Coated Tablet)	Not Reported
	Aliskiren	S	Transplacental	300 [Mg/D]; 0-4.6 Gestational Week	Not Reported
	Dalteparin Sodium	S	Transplacental		Not Reported
	Heparin (Salt Not Specified)	S	Transplacental	Unk Unk,Unk	Not Reported
	Nicotine	S	Transplacental	From Gestational Week 0-14	Not Reported
	Enoxaparin Sodium	S	Transplacental	200 Mg/D (2x100)	Not Reported
	Rituximab	S	Transplacental	Last Time In December 2011: Pre Or Periconceptional	Not Reported
	Clexane	S	Transplacental	200 Mg/D (2x100)	Not Reported
	Heparin Lmw	S	Transplacental	Unk	Not Reported
	Acetylsalicylic Acid	S	Transplacental	From Gestational Week 0-14	Not Reported
	Metamizole	S	Transplacental	From Gestational Week 0-14	Not Reported
	Prednisolone	S	Transplacental	From Gestational Week 0-14	Not Reported
	Novaminsulfon	S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5	Not Reported
	Cytotec	C	Transplacental	Unk; 13.6 Gestational	Not Reported

				Week		
	Cyclophosphamide	C	Transplacental	3000 [Mg Cumulative]; Preconceptional		Not Reported
	Mifegyne	C	Transplacental	Unk; 13.6 Gestational Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	15933671	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656078-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			C				Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	16972574	EXPEDITED (15-DAY)		DE, OT	CA-ABBVIE-19K-028-2978585-00		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sepsis; Synovitis; Terminal State; Thrombosis	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S				Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Simponi			C	Unknown			Not Reported
	Rituximab W/Urelumab			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17182091	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019231676			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline

Administered; Discomfort; Drug Ineffective; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Diclofenac Sodium	S	Unknown	Unk	Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Desoximetasone	S	Oral	Unk	Glaxosmithkline
	Folic Acid	S	Unknown	1 Milligram	Glaxosmithkline
	Folic Acid	S	Unknown	5 Milligram	Glaxosmithkline
	Folic Acid	S	Unknown	1 Milligram	Glaxosmithkline
	Folic Acid	S	Unknown	5 Milligram	Glaxosmithkline
	Cimzia (Certolizumab Pegol)	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Tocilizumab	S	Subcutaneous	Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Etanercept	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram Solution	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Solution	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram Solution	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil (Hydroxychloroquine)	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Subcutaneous	500 Milligram	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17422218	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-04558		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Prescribed Underdose; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Azathioprine			S				Not Reported
	Celebrex			S	Unknown	Unknown		Not Reported
	Celebrex			S	Unknown			Not Reported
	Celecoxib			S	Unknown	Unknown		Not Reported
	Celecoxib			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported

Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Plaquenil	S	Unknown	Unknown	Not Reported
Prednisone	S	Unknown		Not Reported
Simponi	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
Sulfasalazine	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Acetaminophen/Codeine Phosphate	C	Unknown	Unknown	Not Reported
Altace	C	Unknown		Not Reported
Altace	C	Unknown		Not Reported
Apo-Gabapentin	C	Unknown		Not Reported
Apo-Gabapentin	C	Oral		Not Reported
Atorvastatin Calcium	C	Oral		Not Reported
Atorvastatin Calcium	C	Unknown		Not Reported
Atorvastatin Calcium	C	Unknown		Not Reported
Cipralex (Escitalopram)	C	Unknown		Not Reported
Citalopram Hydrobromide	C	Unknown		Not Reported

Conjugated Estrogens	C	Unknown			Not Reported
Conjugated Estrogens	C	Unknown			Not Reported
Cymbalta	C	Unknown			Not Reported
Cymbalta	C	Unknown			Not Reported
Cymbalta	C	Unknown			Not Reported
Escitalopram	C	Unknown			Not Reported
Estrace	C	Unknown			Not Reported
Gabapentin	C	Unknown			Not Reported
Gabapentin	C	Oral			Not Reported
Hydrochlorothiazide	C	Unknown			Not Reported
Hydromorphone Hydrochloride	C	Oral			Not Reported
Hydromorphone Hydrochloride	C	Oral			Not Reported
Mupirocin	C	Topical	Unknown		Not Reported
Pantoloc (Pantoprazole)	C	Unknown			Not Reported
Shark Liver Oil	C	Unknown	Unknown		Not Reported
Tapentadol Hydrochloride	C	Unknown			Not Reported
Taro-Mupirocin	C	Topical	Unknown		Not Reported
Tramadol Hydrochloride	C	Oral			Not Reported
Tramadol Hydrochloride	C				Not Reported
Tramacet	C	Oral			Not Reported
Tramacet	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17631825	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200337612			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug	Simponi			S	Subcutaneous			Janssen
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Intolerance; Fatigue; Inflammatory Marker Increased; Keratitis	Orencia		S	Unknown	Not Reported
	Plaquenil /00072602/		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17643631	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2020-015943			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Dermatitis Bullous; Drug Reaction With Eosinophilia And Systemic Symptoms; Pemphigus; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Azithromycin			S	Unknown	Unk		Aurobindo
	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo
	Aciclovir			S	Unknown	Unk		Aurobindo
	Cefixime			S	Unknown	Unk		Aurobindo
	Ceftriaxone			S	Unknown	Unk		Aurobindo
	Fluconazole			S	Unknown	Unk		Aurobindo
	Gentamicin			S	Unknown	Unk		Not Reported
	Lamotrigine			S	Unknown	Unk		Aurobindo
	Metronidazole			S	Unknown	Unk		Aurobindo
	Paracetamol			S	Unknown	Unk		Aurobindo
	Risperidone			S		Unk		Aurobindo
	Terbinafine			S	Unknown	Unk		Aurobindo
	Ampicillin;Sulbactam			S	Unknown	Unk		Not Reported
	Ketoprofen			S	Unknown	Unk		Not Reported
	Clarithromycin			S	Unknown	Unk		Not Reported
	Aspirin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Vancomycin			S	Unknown	Unk		Not Reported
	Enoxaparin			S	Unknown	Unk		Not Reported
	Ceftazidime			S	Unknown	Unk		Not Reported
	Oxacillin			S	Unknown	Unk		Not Reported
	Clindamycin			S	Unknown	Unk		Not Reported

	Carbamazepine	S	Unknown	Unk		Not Reported
	Phenytoin	S	Unknown	Unk		Not Reported
	Phenobarbital	S	Unknown	Unk		Not Reported
	Teicoplanin	S	Unknown	Unk		Not Reported
	Rufinamide	S	Unknown	Unk		Not Reported
	Cotrimoxazole	S	Unknown	Unk		Not Reported
	Cisplatin	S	Unknown	Unk		Not Reported
	Fluorouracil	S	Unknown	Unk		Not Reported
	Asa	S	Unknown	Unk		Not Reported
	Lithium	S	Unknown	Unk		Not Reported
	Methylphenidate	S	Unknown	Unk		Not Reported
	Acetylcysteine	S	Unknown	Unk		Not Reported
	Ibuprofen	S	Unknown	Unk		Not Reported
	Acetaminophen	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17647577	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200403510		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Discomfort; Drug Ineffective; Hyperaesthesia; Memory Impairment; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Cimzia			C	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17648818	EXPEDITED (15-DAY)		OT	IT-GLAXOSMITHKLINE-IT2020061361		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Off Label Use; Pyrexia; Systemic Lupus Erythematosus; Therapy Non-Responder	Belimumab			S	Unknown	Unk		Glaxosmithkline
	Belimumab			S	Unknown	Unk		Glaxosmithkline
	Belimumab			S	Unknown	Unk		Glaxosmithkline
	Tacrolimus			S	Unknown	Unk Unk, Qd		Glaxosmithkline
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisone			S	Unknown	12.5 Mg, Qd		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd		Not Reported
	Prednisone			S	Unknown	7.5 Mg, Qd		Not Reported
	Prednisone			S	Unknown	10 Mg, Qd		Not Reported
	Prednisone			S	Unknown	50 Mg, Qd		Not Reported
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk, Qd		Not Reported
	Rituximab			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	Unk (Pulses)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17668607	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030971		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine Sulfate	S	Intravenous (not otherwise specified)		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Leflunomide	S	Oral		Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Desoximetasone	C	Unknown	10 Milligram, Qd	Not Reported
Diclofenac	C	Unknown	100 Milligram, Qd	Not Reported
Methotrexate	C	Unknown		Not Reported
Voltaren [Diclofenac Sodium]	C	Unknown	100 Milligram, Qd	Not Reported
Xeljanz	C	Unknown		Not Reported
Zostavax	C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17668861	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1720		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Simponi	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Prednisolone	S	Unknown	Not Reported
	Prednisone	S	Endocervical	Not Reported
	Risedronate Sodium	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Cyclobenzaprine	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Prednisone Acetate	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17668878	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1723			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Blister; Drug Ineffective; Feeling Abnormal; Gastrointestinal Disorder; Hepatic Enzyme Abnormal; Inappropriate Schedule Of Product Administration; Mouth Haemorrhage; Mouth Ulceration; Musculoskeletal Discomfort; Nausea;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Lipitor			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported

Psoriatic Arthropathy; Pyrexia; Synovitis	Cosentyx	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Dovobet	C	Unknown	Not Reported
	Flovent	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Multi Vitamins & Minerals	C	Unknown	Not Reported
	Omeprazole	C	Unknown	Not Reported
	Ventolin	C	Unknown	Not Reported
	Vitamin D2	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17668879	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1721		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Endocervical			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)		
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17668886	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1730			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Musculoskeletal Stiffness; Polyarthritis; Product Use In Unapproved Indication; Skin Lesion; Uveitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Aralen Hydrochloride			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669411	EXPEDITED (15-DAY)		HO	GR-TEVA-2020-GR-1222919		56 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia; Urinary Tract Infection; Urinary Tract Pain	Ciclosporin			S	Oral	50 Mg, 2x/Day		Ivax
	Hydroxychloroquine Phosphate			S	Oral	200 Mg, 1x/Day		Not Reported
	Medrol			S	Oral	4 Mg, 1x/Day		Not Reported
	Thyrohormone			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669462	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Constipation; Drug Hypersensitivity; Drug Ineffective; Rash; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Codeine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Arava			C	Unknown	20 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669590	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096477			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Treatment Failure	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Desoximetasone			C		20 Mg, Qd		Not Reported
	Tylenol Arthritis Pain			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669591	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096338			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Infection; Pneumonia	Arava			S	Oral			Sanofi
	Arava			S	Unknown	Unk		Sanofi

	Hydroxychloroquine	S	Unknown		Sanofi
	Celecoxib	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Sanofi
	Methotrexate	S	Intra-arterial		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Prednisone	S	Unknown	5 Mg	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	1.0 Df, Qw	Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	40 Mg, Qw	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669592	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096116			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Retinal Injury	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Humira			C				Not Reported
	Methotrexate			C		Unk		Not Reported
	Xeljanz			C				Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669596	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA096531		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Hypertensive	Plaquenil			S		200 Mg, Bid		Sanofi

Heart Disease; Peripheral Swelling; Therapeutic Response Changed	Methotrexate		S	Subcutaneous	20 Mg	Not Reported
	Arava		S	Oral	20 Mg	Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669689	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2020M1037212		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy; Herpes Simplex; Herpes Simplex Hepatitis; Thrombocytopenia	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Prednisone			S	Unknown	5 Milligram, Qd		Not Reported
	Acetaminophen			C	Unknown	6 Gram		Mylan
	Metronidazole			C	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669899	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009850			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure Via Breast Milk	Leflunomide			S	Transmammary	Unk		Apotex
	Hydroxychloroquine			S	Transmammary	Unk		Apotex
	Methotrexate			S	Transmammary	Unk		Not Reported
	Enbrel			S	Transmammary	Unk		Not Reported
	Certolizumab Pegol			S	Transmammary	Unk		Not Reported
	Prednisone			C	Transmammary	Unk		Not Reported
	Sulfasalazine			C	Transmammary	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669916	DIRECT		DE				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Torsade De Pointes	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S			1 DAY	Not Reported

	Azithromycin	S			Not Reported
	Azithromycin	S		2 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17670426	EXPEDITED (15-DAY)		HO, OT	NL-TEVA-2020-NL-1222817		31 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure Before Pregnancy; Maternal Exposure During Pregnancy; Pre-Eclampsia; Premature Delivery	Sulfasalazine			S	Oral	2000 Milligram Daily;		Actavis
	Sulfasalazine			S	Oral	2000 Milligram Daily;		Actavis
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram Daily;		Teva
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram Daily;		Teva
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram Daily;		Teva
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Q2w		Not Reported
	Omeprazole			C	Oral	20 Milligram Daily;		Not Reported
	Novorapid			C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17670440	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1223401		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Sudden Death	Levofloxacino (2791a)			S	Unknown			Teva
	Hidroxicloroquina Sulfato (2143su)			S	Oral	200 Mg		Teva
	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Lopinavir+Ritonavir			S	Oral	4 Dosage Forms Daily;		Not Reported
	Enoxaparina Sodica (2482so)			C	Subcutaneous	40 Mg		Not Reported
	Prednisona (886a)			C	Oral	20 Mg		Not Reported
	Ceftriaxona (501a)			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17671067	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096278			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Plaquenil			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S				Sanofi
	Cetirizine Hydrochloride			S				Not Reported
	Folic Acid			S				Not Reported
	Alendronate Sodium			S				Not Reported
	Methotrexate			S				Not Reported
	Prednisone			S				Not Reported
	Sulfasalazine			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17671115	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096445			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Fatigue; Malaise	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Arava			S	Unknown			Sanofi
	Folic Acid			S	Unknown			Not Reported
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Prednisone			S		1 Df, Qw		Not Reported
	Prevacid			C				Not Reported
	Risedronate Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17671152	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1223013		63 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rhabdomyolysis	Hidroxicloroquina (2143a)			S	Oral	2-5 Day: 200mg / 12h		Teva
	Hidroxicloroquina (2143a)			S	Oral	1 Day: 400mg / 12h, 2-5 Day: 200mg / 12h		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17671153	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1223386		68 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	200mg/12h		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Azitromicina (7019a)			S	Oral	500 Milligram Daily; 500mg/24h		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily; 2gr/24h		Not Reported
	Ceftriaxona (501a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17671318	EXPEDITED (15-DAY)		DS	CA-SAMSUNG BIOEPIS-SB-2020-12495			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion	Infliximab			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Abatacept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported

Related Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use In Unapproved Indication; Product Use Issue; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Vascular Access Complication; White Blood Cell Count Increased	Humira	S	Subcutaneous			Not Reported
	Leflunomide	S	Unknown	Unknown		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Unknown	Unknown		Not Reported
	Plaquenil	S	Unknown	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17672057	NON-EXPEDITED			US-CELGENEUS-USA-20200403202		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Otezla			S	Oral	60 Milligram		Celgene
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17672078	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1221322			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Flutter	Hydroxychloroquine Sulfate Watson			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17672447	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-12513			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased	Etanercept			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Single Use Pre-Filled Syringe Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Tocilizumab			S	Unknown	Unknown		Not Reported
	Azathioprine			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17672893	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3363203-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Blister; Drug Ineffective; Feeling Abnormal; Gastrointestinal Disorder; Hepatic Enzyme Abnormal; Inappropriate Schedule Of Product	Humira			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

Administration; Mouth Haemorrhage; Mouth Ulceration; Musculoskeletal Discomfort; Nausea; Psoriatic Arthropathy; Pyrexia; Synovitis	Sulfasalazine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Cimzia	S	Unknown	Not Reported
	Arthrotec	S	Unknown	Not Reported
	Lipitor	S	Oral	Not Reported
	Dovobet	C	Topical	Not Reported
	Folic Acid	C	Oral	Not Reported
	Omeprazole	C	Oral	Not Reported
	Flovent	C	Respiratory (inhalation)	Not Reported
	Ventolin	C	Respiratory (inhalation)	Not Reported
	Vitamin D2	C	Oral	Not Reported
	Multi Vitamin	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17673591	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096533			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Pneumonitis; Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Leflunomide			S		Unk		Sanofi
	Enbrel			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Pneumococcal Vaccine Polysacch 23v			C	Unknown			Not Reported
	Prevnar 13			C	Intramuscular			Not Reported
	Varicella Zoster Vaccine Live			C	Unknown			Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17673602	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030963		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; C-Reactive Protein Increased; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Orencia			S	Endocervical			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram, Qd		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17673612	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020153377			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Pfizer
	Etanercept			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Arava			S	Unknown	20 Mg, 1x/Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17673774	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004002881			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphonia; Malaise; Systemic Lupus Erythematosus Rash	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17673830	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202003002619			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Inflammation; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17674032	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-018904		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Tachyarrhythmia	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Once A Day		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 Gram, Once A Day		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17674037	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018903		63 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram, 1 Total		Not Reported
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17674055	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018905		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Hepatitis	Azithromycin		S	Oral	500 Milligram, Once A Day	Aurobindo
	Dolquine		S	Other	400 Milligram, Once A Day	Not Reported
	Dolquine		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17674074	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031130			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Orencia			S	Endocervical			Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Unk, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Mefenamic Acid			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported
	Prednisone			C	Oral	10 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17674075	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018907		28 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Paracetamol			S	Intravenous (not	1 Gram, 3 Times A Day		Aurobindo

			otherwise specified)		
	Dolquine	S	Oral	400 Milligram, Once A Day	Not Reported
	Dolquine	S			Not Reported
	Ceftriaxone	S	Intravenous (not otherwise specified)	2 Gram, Once A Day	Not Reported
	Ceftriaxone	S			Not Reported
	Azithromycin	S	Oral	500 Milligram, Once A Day	Not Reported
	Azithromycin	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17675095	DIRECT	Y	DE			88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Pulmonary Embolism; Unresponsive To Stimuli	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	12776522	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-024854		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Hereditary Angioedema; Infection; Intentional Product Use Issue; Joint Swelling; Liver Function	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Qmo		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	4 Mg/Kg, Unk		Not Reported
	Actemra			S	Unknown	40 Milligram/Kilogram		Not Reported
	Actemra			S	Unknown	4 Milligram		Not Reported
	Arava			S	Oral	10 Mg, Qd		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported

Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Humira	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Cyclical	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
	Methotrexate	S	Unknown	25 Mg, Qwk	Not Reported
	Methotrexate	S	Unknown	250 Milligram, Qwk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	200 Mg, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
	Simponi	S	Subcutaneous	50 Mg, Qmo	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Oral	50 Milligram, Bid	Not Reported
	Prevacid	C	Unknown	30 Mg, Bid	Not Reported
	Prednisone	C	Unknown	5 Mg, Qd	Not Reported
	Prednisone	C	Unknown	50 Milligram, Qd	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	14409544	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2018AP005298		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction;	Diclofenac Potassium			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported

Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Arava	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Motrin	S	Unknown	Unk	Not Reported
	Naprosyn /00256201/	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Oral	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Voltaren /00372301/	S	Unknown	Unk	Not Reported
	Sulfamethoxazole W/Trimethoprim	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Tramadol Hcl	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	14933830	EXPEDITED (15-DAY)		DS, OT	GB-SA-2018SA139931		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Leflunomide			S				Sanofi
	Plaquenil			S	Oral	400 Mg, Qd		Sanofi
	Erythromycin			S				Sanofi
	Arava			S				Sanofi
	Demerol			S				Sanofi
	Bisoprolol Fumarate			S	Unknown	Tablet		Not Reported
	Methotrexate			S	Oral	1 Df, Qw		Not Reported
	Metronidazole			S				Sanofi
	Norfloxacin			S				Not Reported
	Cefaclor			S				Not Reported
	Erythromycin			S				Sanofi
	Celecoxib			S	Oral	200 Mg, Qd		Not Reported
	Pregabalin			S				Not Reported
	Sulfasalazine			S				Not Reported
	Prednisone			S	Unknown			Not Reported

Erythromycin Estolate	S		Unk	Not Reported
Levofloxacin	S			Not Reported
Arthrotec	S			Not Reported
Meperidine Hydrochloride	S			Not Reported
Plaquenil	S			Sanofi
Norfloxacin	S		400 Mg	Not Reported
Celecoxib	S	Oral	200 Mg	Not Reported
Celecoxib	S	Oral	200 Mg, Qd	Not Reported
Prednisone	S			Not Reported
Bisoprolol Fumarate	S			Not Reported
Bisoprolol Salt Not Specified	S			Not Reported
Humira	S	Subcutaneous	400 Mg	Not Reported
Diclofenac Sodium/Misoprostol	S			Not Reported
Methotrexate Sodium	S			Not Reported
Pethidine Hydrochloride	S			Sanofi
Sulfasalazine	S		500 Mg	Not Reported
Levofloxacin Hemihydrate	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	15621514	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557370-00		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Apo Hydroxyquine	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Cimzia	S	Subcutaneous		Not Reported
Leflunomide	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	16205860	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1039198		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cataract; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Metformin Hydrochloride			S	Unknown	1000 Milligram Daily;		Actavis
	Desoximetasone			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Altace			C	Unknown	5 Milligram Daily;		Not Reported
	Asa			C	Unknown	81 Milligram Daily;		Not Reported
	D-Alpha Tocopherol/Fish Oil			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Oral	15 Milligram Daily;		Not Reported
	Rosuvastatin Calcium			C	Unknown	20 Milligram Daily;		Not Reported

	Vitamin D /00107901/	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	16582688	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2852957-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Joint Swelling; Joint Swelling; Ocular Toxicity; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Naproxen			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Indocid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	16844994	EXPEDITED (15-DAY)		OT	GR-PFIZER INC-2019378939		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Exemestane			S		Unk		Pfizer
	Lansoprazole			S	Unknown	Unk		Pfizer
	Ramipril			S	Unknown	Unk		Pfizer
	Prednisolone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Azathioprine	S	Unknown	Unk		Not Reported
Belimumab	S	Unknown	Unk		Not Reported
Dicumarol	S	Unknown	Unk		Not Reported
Thyroxine	S	Unknown	Unk		Not Reported
Thyroxine	S	Oral	Unk		Not Reported
Metformin	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Metformin Hydrochloride	S		Unk		Not Reported
Levothyroxine Sodium	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17180775	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019054476		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Decreased Appetite; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity;	Cimzia			S	Subcutaneous			Ucb
	Cimzia			S				Ucb
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Ucb
	Cetirizine Hydrochloride			S				Ucb
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S		Unk		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		400 Milligram, Once Daily (Qd)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	400 Milligram, Weekly (Qw)		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Monthly (Qm)		Not Reported
	Simponi			S	Subcutaneous			Not Reported

Hypertension; Hypoaesthesia; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Malaise; Maternal Exposure During Pregnancy; Mobility Decreased; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Simponi	S		Solution And Suspension For Injection In Pre-Filled Syringe	Not Reported
	Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Humira	S	Subcutaneous	Solution	Ucb
	Orencia	S		Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
	Xeljanz	S	Oral	5 Milligram, 2x/Week	Not Reported
	Apo Prednison	S			Not Reported
	Apo Prednison	S		Unk	Not Reported
	Arava	S	Oral		Not Reported
	Cortisone Acetate	S		25 Milligram	Not Reported
	Folic Acid	S		1 Milligram	Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Folic Acid	S		0.5 Milligram	Not Reported
	Fosamax	S	Oral		Not Reported
	Methotrexate	S		20 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	S		20 Milligram, Once Daily (Qd)	Not Reported
	Methotrexate	S	Oral	25 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	S	Oral	20 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine	S		400 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Phthalylsulfathiazole	S			Not Reported

Prednisone	S			Not Reported
Pseudoephedrine Hcl	S			Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution	Not Reported
Rituxan	S	Subcutaneous	Solution	Not Reported
Salazopyrine	C	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	1000 Milligram, Once Daily (Qd)	Not Reported
Sulfathalidine	S			Not Reported
Orencia	S	Subcutaneous		Not Reported
Leflunomide	S	Oral		Not Reported
Hydroxychloroquine Phosphate	S		400 Milligram, Once Daily (Qd)	Not Reported
Hydroxychloroquine Phosphate	S		400 Milligram, Once Daily (Qd)	Not Reported
Tocilizumab	S	Subcutaneous		Not Reported
Etanercept	S		Unk	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
Winpred	S	Oral		Not Reported
Paracetamol	S			Not Reported
Stelara	S			Not Reported
Diclofenac Sodium	S			Not Reported
Topicort Lp	S	Subcutaneous	Unk	Not Reported
Topicort Lp	S	Oral		Not Reported
Sarilumab	S			Not Reported
Ustekinumab	S	Intravenous (not otherwise specified)	45 Milligram	Not Reported
Apo-Hydroxyquine	S			Not Reported
Otezla	S	Oral	3 Milligram, 2x/Day (Bid)	Not Reported
Otezla	S	Oral	3 Milligram, 2x/Day (Bid)	Not Reported
Otezla	S	Oral		Not Reported
Otezla	S	Oral		Not Reported

	Reactine [Cetirizine Hydrochloride]	S			Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Desoximetasone	S	Oral		Not Reported
	Methotrexate	C	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	C	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Tofacitinib Citrate	C	Oral	5 Milligram, Weekly (Qw)	Not Reported
	Desoximetasone	C	Oral	25 Milligram, Weekly (Qw)	Not Reported
	Diclofenac	C		50 Milligram, Once Daily (Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17302274	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA014510		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Leflunomide			S	Unknown	Unk		Sanofi
	Arava			S	Unknown	Unk		Sanofi
	Prednisone			S	Unknown	Unk		Not Reported
	Pethidine Hydrochloride			S	Unknown	Unk		Sanofi
	Pethidine Hydrochloride			S	Unknown	Unk		Sanofi
	Methotrexate			S	Oral	Unk Unk, Qw		Not Reported
	Metronidazole			S	Unknown	Unk		Sanofi
	Prednisone			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Demerol			S	Unknown	Unk		Sanofi
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Norfloxacin			S	Unknown	400 Mg		Not Reported
	Bisoprolol Salt Not Specified			S	Unknown	Unk		Not Reported

Bisoprolol Fumarate	S	Unknown	Unk		Not Reported
Cefaclor	S	Unknown	Unk		Not Reported
Celecoxib	S	Oral	200 Mg		Not Reported
Celecoxib	S	Oral	200 Mg, Qd		Not Reported
Celecoxib	S	Oral	200 Mg, Qd		Not Reported
Erythromycin	S	Unknown	Unk		Sanofi
Erythromycin	S	Unknown	Unk		Sanofi
Erythromycin Estolate	S	Unknown	Unk		Not Reported
Levofloxacin	S	Unknown	Unk		Not Reported
Pregabalin	S	Unknown	Unk		Not Reported
Norfloxacin	S	Unknown	Unk		Not Reported
Plaquenil	S	Oral	400 Mg, Qd		Sanofi
Plaquenil	S	Oral	Unk		Sanofi
Arthrotec	S	Unknown	Unk		Not Reported
Levofloxacin Hemihydrate	S	Unknown	Unk		Not Reported
Diclofenac Sodium/Misoprostol	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	400 Mg		Not Reported
Methotrexate Sodium	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17315972	EXPEDITED (15-DAY)		OT	CA-SA-2020SA014485			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Use Issue; Rheumatoid Arthritis	Leflunomide			S	Unknown	20.0 Mg, Qd (20.0 Milligram 1 Every 1 Days)		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid (2 Every 1 Days)		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qw		Sanofi
	Actemra			S	Unknown	Unk		Not Reported

	Enbrel	S	Unknown	25 Mg (Every 2 Weeks)	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qow (Once Every 2 Weeks)	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	C		Unk	Not Reported
	Wellbutrin	C		Unk	Not Reported
	Xeljanz	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17332071	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-01520		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder;	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported

Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Alendronate Sodium	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown	Unknown	Not Reported
	Alendronic Acid	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Codeine	S	Unknown	Unknown	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported

Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Myochrysine	S	Intramuscular	(Solution)	Not Reported

Myochrysine	S	Intramuscular		Not Reported
Myochrysine	S	Parenteral		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Orencia	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown (Powder For Solution Intravenous)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown (Powder For Solution Intravenous)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituximab	S	Unknown		Not Reported
Rituximab	S	Unknown		Not Reported
Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Azathioprine	S	Unknown	Unknown	Not Reported
Celebrex	S	Unknown	Unknown	Not Reported
Naproxen	S	Unknown	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Unknown	Not Reported
Ciclosporin	C	Unknown		Not Reported
Ciclosporin	C	Unknown		Not Reported

	Prednisolone	C	Unknown	Not Reported
	Prednisolone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17365657	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023782			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate			S				Sanofi
	Prednisone			S				Not Reported
	Folic Acid			S		5 Mg		Not Reported
	Alendronate Sodium			S				Not Reported
	Hydroxychloroquine			S				Sanofi
	Leflunomide			S	Oral			Sanofi
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S				Not Reported
	Methotrexate			S				Not Reported
	Arava			S				Sanofi
	Prednisone			S				Not Reported
	Sulfasalazine			S		500 Mg		Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

					otherwise specified)					
	Rituxan			S	Intravenous (not otherwise specified)					Not Reported
	Simponi			S	Subcutaneous					Not Reported
	Simponi			S	Subcutaneous					Not Reported
	Desoximetasone			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17486747	EXPEDITED (15-DAY)		OT	IT-VELOXIS PHARMACEUTICALS-2020VELIT-000200		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Off Label Use	Envarsus			S	Unknown	Unk, Qd		Chiesi
	Mycophenolate Mofetil			S	Unknown	Unk Unk, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Not Reported
	Prednisone			S	Unknown	50 Mg Qd, Tapering Dose		Not Reported
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisone			S	Unknown	25 Mg Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd		Not Reported
	Prednisone			S	Unknown	15 Mg Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	10 Mg Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	7.5 Mg Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	12.5 Mg Qd, Dose Tapering		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Immunoglobulin I.V			C		Unk		Not Reported
	Rituximab			C		Unk		Not Reported

Methylprednisolone	C	Unk (Pulses)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17511082	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200240044			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury; Off Label Use	Stelara			S	Subcutaneous			Janssen
	Simponi			S	Subcutaneous			Janssen
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Otezla			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17517037	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200243788			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Psoriatic Arthropathy; Synovitis	Simponi			S	Subcutaneous			Janssen
	Stelara			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Methotrexate		S	Unknown	Not Reported
	Otezla		S	Unknown	Not Reported
	Plaquenil /00072602/		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17553274	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019148132		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	100 Milligram		Not Reported
	Apo Prednison			S	Unknown	7 Milligram, Qd		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Celebrex			S				Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	1 Milliliter, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	7 Milligram, Qd		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	7 Milligram, Qd		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Celecoxib			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17558095	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200316684		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Aspirin /00002701/			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Remicade			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17567096	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318557		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Simponi	S	Subcutaneous	Janssen
	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Actemra	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Folic Acid	C		Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Pantoprazole Sodium	C	Unknown	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
	Xeljanz	C		Not Reported
	Zopiclone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17605625	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200333276		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Middle Insomnia; Musculoskeletal Stiffness; Pain In Extremity; Rash	Simponi			S	Subcutaneous			Janssen
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17605640	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200333287		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Toxicity; Rheumatoid Arthritis; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17648281	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200403508		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arthralgia; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Headache; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Nausea; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw;	Simponi			S	Subcutaneous			Janssen
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported

Proteinuria; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Treatment Failure; Vasculitis; Weight Decreased	Penicillamine	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Amitriptyline Hydrochloride	C		Not Reported
	Doxycycline	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Tobramycin	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17651850	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200316464		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Stomatitis	Simponi			S	Subcutaneous			Janssen
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tylenol Arthritis Pain			C	Unknown			Not Reported
	Tylenol Arthritis Pain			C				Not Reported

	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17658993	EXPEDITED (15-DAY)		LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030043		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ilaris			S	Subcutaneous	Unk		Not Reported
	Ilaris			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomida			S	Unknown	Unk		Not Reported
	Marijuana			S	Unknown	Unk		Not Reported

Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown		Not Reported
Minocycline	S	Unknown	Unk	Not Reported
Oxycodone	S	Unknown	10 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Unknown		Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Xeljanz	S	Oral	Unk Unk, Bid	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
Lyrica	C	Unknown	Unk	Not Reported
Kineret	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17670489	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1222995		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hyperbilirubinaemia; Hypocoagulable State	Hydroxychloroquine			S	Oral	400 Milligram Daily; 200 Mg/12h		Teva
	Kaletra			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17673141	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031084			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Neck Pain; Off Label Use; Spinal Column Injury; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17673245	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018502		53 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Propofol Infusion Syndrome	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S				Aurobindo
	Propofol			S	Intravenous (not otherwise specified)	6.6 Milligram/Kilogram, 1 In Hour, (Sedation)		Not Reported
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Dolquine			S				Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	4 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17673960	NON-EXPEDITED			US-AMGEN-USASP2020061784		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674049	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US-001167			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Dyspnoea Exertional	Hydroxychloroquine			S	Unknown	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674369	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096501			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatotoxicity; Liver Function Test Increased	Hydroxychloroquine			S				Sanofi
	Colchicine			S				Not Reported
	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S				Not Reported
	Methylprednisolone			S				Not Reported
	Sulfasalazine			S				Not Reported
	Azathioprine			S		150 Mg, Qd		Not Reported
	Bromocriptin Ct			S				Not Reported
	Ciclosporin			S				Not Reported
	Dilaudid			S				Not Reported
	Doxycycline Hyclate			S				Not Reported

	Enbrel	S					Not Reported
	Gold	S					Not Reported
	Humira	S	40 Mg				Not Reported
	Mercaptopurin	S					Not Reported
	Pamidronate Disodium	S					Not Reported
	Tenoxicam	S					Not Reported
	Ustekinumab	S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674370	EXPEDITED (15-DAY)		OT	CA-SA-2020SA097034			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Spinal Compression Fracture	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S				Sanofi
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Xeljanz			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674433	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020154341		48 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia; Overdose	Pantoprazole			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Tacrolimus Monohydrate			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Pentasa			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674454	EXPEDITED (15-DAY)		HO	ES-ABBVIE-20K-144-3365014-00		36 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatitis Acute	Kaletra 200/50		S	Oral	Not Reported
	Kaletra 200/50		S		Not Reported
	Azitromicina		S	Oral	Not Reported
	Azitromicina		S		Not Reported
	Dolquine		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674455	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3365006-00		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mixed Liver Injury	Kaletra 200/50			S	Oral			Not Reported
	Kaletra 200/50			S				Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2gr/24h		Not Reported
	Ceftriaxona			S				Not Reported
	Hidroxicloroquina			S	Oral			Not Reported
	Hidroxicloroquina			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674480	EXPEDITED (15-DAY)		HO	ES-ABBVIE-20K-144-3365040-00		49 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Hepatitis; Hypokalaemia	Kaletra 200/50			S	Oral			Not Reported
	Kaletra 200/50			S				Not Reported
	Interferon Beta-1b			S	Subcutaneous			Not Reported
	Interferon Beta-1b			S				Not Reported
	Dolquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674601	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1222314			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Gout; Hypertension; Palpitations	Metformin		S	Unknown	Actavis
	Sumatriptan Succinate		S	Unknown	Teva
	Colchicine		S	Unknown	Not Reported
	Januvia		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674602	EXPEDITED (15-DAY)		DE	CA-TEVA-2020-CA-1222322		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Metformin			S	Unknown	1000 Milligram Daily;		Actavis
	Alendronate Sodium			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Furosemide			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Ipratropium Bromide/Salbutamol Sulfide			S	Unknown			Not Reported
	Lipitor			S	Unknown			Not Reported
	Losec [Omeprazole]			S	Unknown			Not Reported
	Nitrazadon			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Salmeterol Xinafoate			S	Unknown			Not Reported
	Tylenol[Paracetamol]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674609	EXPEDITED (15-DAY)		OT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-243893		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mycobacterium Marinum	Hydroxychloroquine			S	Unknown	Unk		Sun

Infection	Methotrexate	S	Unknown	Unk		Sun
	Prednisolone	S	Unknown	20 Milligram, Unk		Taro
	Prednisolone	S	Unknown	40 Milligram, Daily		Taro
	Sulfasalazine	S	Unknown	Unk		Sun
	Leflunomide	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674739	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1222306		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Product Use In Unapproved Indication; Thrombosis; Uterine Disorder	Metformin Hydrochloride			S	Unknown			Actavis
	Metformin Hydrochloride			S				Actavis
	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xarelto			C	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674823	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1741		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Fibromyalgia;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

Lymphoedema; Obesity; Pneumocystis Jirovecii Pneumonia; Pulmonary Embolism	Enbrel		S	Unknown	Not Reported
	Actemra		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Calcium/Vitamin D3		C	Unknown	Not Reported
	Hydrocortisone		C	Unknown	Not Reported
	Pantoloc		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Xarelto		C	Unknown	Not Reported
	Tylenol Arthritis Pain		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674993	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2020M1036998		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Granuloma Skin; Mycobacterium Marinum Infection	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Mylan
	Prednisolone			S	Unknown	Low-Dose		Mylan
	Prednisolone			S	Unknown	20 Milligram(Dose Was Increased To 40mg Daily)		Mylan
	Sulfasalazine			S	Unknown			Mylan
	Hydroxychloroquine			S	Unknown			Mylan
	Metoprolol			C	Unknown			Mylan
	Amlodipine			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675107	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020153341			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Red Blood Cell Sedimentation Rate Increased	Methotrexate Sodium			S	Unknown	10 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	50 Mg, Weekly		Pfizer
	Etanercept			S	Unknown			Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Gold/Hyoscyamus Niger/Onopordum Acanthium/Primula Veris [Homeopathic]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675138	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020153374			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Constipation; Drug Hypersensitivity; Drug Ineffective; Rash; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown			Pfizer
	Codeine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Arava			C	Unknown	20 Mg, 1x/Day		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675164	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2607481-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dizziness; Drug Ineffective; Impaired Work Ability; Joint Stiffness; Joint Swelling; Musculoskeletal Pain;	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported

Musculoskeletal Stiffness; Musculoskeletal Stiffness; Nausea; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Azathioprine	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Naproxen	S	Unknown	Not Reported
	Metoprolol	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Pms Azithromycin	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675304	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2020-010799			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Graft Versus Host Disease In Skin	Prednisolone			S	Unknown			Bausch And Lomb
	Ciclosporin			S	Unknown			Not Reported
	Ibrutinib			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sirolimus			S	Unknown			Not Reported
	Bactrim Ds			C				Not Reported
	Quetiapine			C				Not Reported
	Valaciclovir			C				Not Reported
	Lamotrigine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675370	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1223716		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Hidroxicloroquina (2143a)			S	Oral	200mg/12h		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Ceftriaxona (501a)			S	Intravenous (not	2gr/24h,		Not Reported

				otherwise specified)			
	Ceftriaxona (501a)		S				Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid		S	Oral	2 Comp/12h, 2 Dosage Forms		Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675600	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA096344		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Plaquenil			S				Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Sulfasalazine			S		1 G		Not Reported
	Leflunomide			S		20 Mg		Sanofi
	Methotrexate			S		25 Mg		Not Reported
	Certolizumab Pegol			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxyquinoline Sulfate			S				Not Reported
	Neoral			S				Not Reported
	Rapamune			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tacrolimus			S	Oral	2 Mg, Q12h		Not Reported
	Tacrolimus			S	Oral	3 Mg, Q12h		Not Reported
	Imuran [Azathioprine]			C		25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675601	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096537		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Hydroxychloroquine Sulfate	S	Oral	400 Mg	Sanofi
	Methotrexate	S	Subcutaneous	25 Mg	Not Reported
	Minocycline Hydrochloride	S			Not Reported
	Arava	S	Oral		Sanofi
	Sulfasalazine	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Xeljanz	S		5 Mg, Bid	Not Reported
	Enbrel	S			Not Reported
	Azathioprine	S		100 Mg	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Amoxil [Amoxicillin]	C			Not Reported
	Leflunomide	C			Not Reported
	Amoxicillin Sodium And Clavulanate Potassium	C			Not Reported
	Bcg Vaccine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675746	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096830		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Laboratory Test Abnormal	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S		20 Mg, Qd (Every 1 Days)		Sanofi
	Methotrexate			S				Not Reported
	Actemra			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			C				Not Reported
	Hyzaar			C				Not Reported
	Venlafaxine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675748	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096669		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Gastrointestinal Disorder; Inflammation; Insomnia; Nodule; Pain In Extremity; Pollakiuria; Rheumatoid Arthritis	Hydroxychloroquine Sulfate		S	Unknown	200 Mg	Sanofi
	Methotrexate		S	Subcutaneous	1 Df, Qw	Not Reported
	Methotrexate		S	Oral	Unk	Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Leflunomide		S	Unknown	10 Mg	Sanofi
	Leflunomide		S	Unknown	20 Mg	Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675757	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096873			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Arava			S	Oral	20 Mg		Sanofi
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			C	Oral	5 Mg		Not Reported
	Leflunomide			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675841	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA096882		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Paracetamol			S		Unk		Not Reported
	Arava			S		20 Mg, Qd		Sanofi

Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Sulfasalazine	S		Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S		50 Mg, Qw	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Codeine	C		Unk	Not Reported
	Leflunomide	C		20 Mg, Qd	Not Reported
	Meloxicam	C		Unk	Not Reported
	Methotrexate	C		Unk Unk, Qw	Not Reported
	Synthroid	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675867	EXPEDITED (15-DAY)		OT	NVSC2020DE099946		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mycobacterium Marinum Infection	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Metoprolol			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675975	EXPEDITED (15-DAY)		OT	CA-SA-2020SA097036		71 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Intolerance	Hydroxychloroquine Sulfate	S	Sanofi
	Leflunomide	S	Sanofi
	Sulfasalazine	S	Not Reported
	Adalimumab	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17676188	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1038560		54 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Headache; Palpitations	Risedronate			S	Oral	35 Milligram, Total		Not Reported
	Cortancyl			S	Oral	Unk		Mylan
	Plaquenil /00072602/			S	Oral	1 Dosage Form, Qd		Mylan
	Pantoprazole			C				Mylan
	Izalgi			C				Mylan
	Levothyrox			C				Mylan
	Diffu K			C				Mylan
	Atorvastatine /01326101/			C				Mylan
	Clopidogrel			C				Mylan
	Procoralan			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17676221	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1223885		43 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily; 500 Mg/24h		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily; 200mg/12h		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily; 2 Gr/24h		Not Reported
	Ceftriaxona (501a)			S				Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	2 Doses In Total		Not Reported

	Tocilizumab (8289a)	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17676292	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096405		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropod Sting; Drug Hypersensitivity; Drug Ineffective; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Codeine			S				Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17676418	DIRECT	Y	OT			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Hydroxychloroquine			S	Oral			Not Reported
	Atorvastatin			S	Oral			Not Reported
	Kaletra 200/50			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17676757	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1222320			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gout; Pneumonia	Metformin			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Januvia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

	Actemra	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17676812	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1224309		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Azithromycine Anhydre			S	Oral	500 Mg		Not Reported
	Plaquenil			S	Oral	600 Mg		Not Reported
	Ceftriaxone Base			C	Unknown			Not Reported
	Inipomp			C	Unknown			Not Reported
	Rovamycine			C	Unknown			Not Reported
	Paracetamol			C	Unknown			Not Reported
	Xarelto 10 Mg, Comprimé Pelliculé			C	Oral			Not Reported
	Diffu K			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17677150	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA097010		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cellulitis; Musculoskeletal Discomfort	Plaquenil			S		Unk		Sanofi
	Arava			S		Unk		Sanofi
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17677151	EXPEDITED (15-DAY)		OT	CA-SA-2019SA083124		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Contraindication To Medical Treatment; Drug	Arava			S	Unknown	20 Mg		Sanofi
	Plaquenil			S	Unknown	200 Mg, Bid		Sanofi

Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Ovarian Disorder; Pulmonary Toxicity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Visual Impairment	Hydroxychloroquine	S	Unknown			Sanofi
	Methotrexate	S	Unknown	15 Mg, Qw		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Cimzia	S	Subcutaneous	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Actemra	S	Unknown	567 Mg, Q4w		Not Reported
	Rituxan	S	Unknown	Unk		Not Reported
	Celebrex	C	Unknown	Unk		Not Reported
	Inflectra [Infliximab]	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17677153	EXPEDITED (15-DAY)		OT	CA-SA-2017SA043120		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Infection; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Off Label Use; Pain; Synovitis	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Naproxen			S	Unknown	Unk Unk,Unk		Not Reported
	Naproxen			S				Not Reported
	Naproxen Sodium			S		Unk		Not Reported
	Sulfasalazine			S	Oral	500 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	2 G		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Methotrexate Sodium			S				Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported

Orencia	S	Unknown	1 Df, Qm		Not Reported
Rituximab	S				Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported
Risedronate	C	Oral	35 Mg, Qw		Not Reported
Arava	C	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17677300	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020016052		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S		400 Milligram, Once Daily (Qd)		Not Reported
	Methotrexate			S	Oral	25 Milligram, Weekly (Qw)		Not Reported
	Naproxen			C				Not Reported
	Hydroxyzine			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17677732	EXPEDITED (15-DAY)		HO	SE-BAUSCH-BL-2020-011319		16 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Fatigue; Intentional Overdose; Intentional Self-Injury; Somnolence; Tachycardia	Prednisolone			S	Oral	10-15 Pcs		Not Reported
	Sertraline			S	Oral			Not Reported
	Plaquenil			S	Oral	10-15 Pcs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17677745	EXPEDITED (15-DAY)		DS, HO, OT	US-ADVANZ PHARMA-202004002453			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronary Artery Occlusion	Hydroxychloroquine			S				Concordia
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17677821	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-018906		95 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Levofloxacin			S	Intravenous (not otherwise specified)	500 Milligram, Once A Day		Aurobindo
	Risperidone			S	Oral	1 Milligram, Once A Day		Aurobindo
	Quetiapine			S	Oral	25 Milligram, Once A Day		Aurobindo
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Two Times A Day		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Once A Day		Not Reported
	Clindamycin Hydrochloride			C	Intravenous (not otherwise specified)	600 Milligram, Four Times/Day		Not Reported
	Losartan			C	Oral	50 Milligram, Once A Day		Not Reported
	Lorazepam			C	Oral	1 Milligram, Once A Day		Not Reported
	Furosemide			C	Oral	40 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17679795	DIRECT	Y	OT			32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Hydroxychloroquine 200mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	12440760	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-042673		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Anaphylactic Reaction;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported

Arthralgia; Arthropathy; Blood Glucose Increased; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Lupus-Like Syndrome; Multiple Allergies; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatic Disorder; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Increased	Enbrel	S	Subcutaneous	Unk	Not Reported
	Lyrica	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Unknown	1.5 Milligram, Bid	Not Reported
	Hydroxychloroquine Phosphate	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qwk	Not Reported
	Mycophenolate Mofetil Hydrochloride	S	Unknown	Unk	Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Apo Mycophenolate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Apo Hydroxyquine	S	Unknown		Not Reported
	Pregabalin	S	Oral		Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Plaquenil S	S	Oral	Unk	Not Reported
	Plaquenil S	S	Unknown	Unk	Not Reported

	Cellcept [Mycophenolate Mofetil]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
	Prednisone	S	Urethral	25 Milligram, Qd	Not Reported
	Prednisone	S	Unknown	1 Dosage Form	Not Reported
	Celecoxib	S	Oral	200 Milligram, Bid	Not Reported
	Piroxicam	C	Unknown	Unk	Not Reported
	Morphine	C	Unknown	Unk	Not Reported
	Levothyroxine	C	Unknown		Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	12889043	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP013260		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Shoulder Arthroplasty; Vomiting;	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Diclofenac			S	Unknown	Unk		Apotex
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Diclofenac Potassium			S	Unknown	Unk		Apotex
	Naproxen			S	Unknown	Unk		Apotex
	Trimethoprim/Sulfamethoxazole			S	Unknown	Unk		Apotex
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Motrin			S	Unknown	Unk		Not Reported
	Naprosyn /00256201/			S	Unknown	Unk		Not Reported
	Gold			S	Unknown			Not Reported

Weight Decreased	Plaquenil /00072602/	S	Oral	Unk		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk		Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
	Vitamin C /00008001/	S	Unknown	Unk		Not Reported
	Tramadol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	13178489	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015826		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthritis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatic Fibrosis; Insomnia; Pain; Rash; Therapeutic Product Effect Incomplete	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Apo-Venlafaxine Xr			S	Oral	150 Mg, Qd		Apotex
	Enbrel			S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	300 Mg, Qd		Not Reported
	Reactine /00884302/			C	Unknown	10 Mg, Qd		Not Reported
	Ultram /00599202/			C	Unknown	Unk		Not Reported
	Zopiclone			C	Unknown	7.5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	13473732	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP016276			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Intentional Product Use Issue; Knee Arthroplasty; Maternal	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Prednisone			S	Oral	Unk		Not Reported
	Prednisone			S				Not Reported
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Diclofenac Sodium			S	Unknown	Unk		Apotex

Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S			Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S			Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S			Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S			Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Humira	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S			Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Reactine /00884302/	S	Unknown	Unk	Not Reported
	Reactine /00884302/	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S			Not Reported
	Methotrexate	S	Intra-arterial	25 Mg, Unk	Not Reported
	Methotrexate	S			Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Plaquenil /00072602/	S			Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	1 G, Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Mg, Unk	Not Reported
	Rituximab	S	Intravenous (not	Unk	Not Reported

					otherwise specified)					
	Xeljanz			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	13710219	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2017AP013547		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Osteoarthritis; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Diclofenac			S	Oral	75 Mg, Bid		Apotex
	Diclofenac			S	Oral	75 Mg, Unk		Apotex
	Diclofenac			S	Oral	1 Df, Unk		Apotex
	Diclofenac			S	Oral	2 Df, Qd		Apotex
	Folic Acid			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Unknown	Unk		Apotex
	Lisinopril			S	Unknown	Unk		Apotex
	Methotrexate			S	Subcutaneous	20 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	1 Df, Q.Wk.		Not Reported
	Pantoprazole Magnesium			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Qd		Not Reported
	Plaquenil /00072602/			S	Oral	1 Df, Qd		Not Reported
	Prinivil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Sulfasalazine			S	Oral	500 Mg, Qd		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Voltaren Sr			S	Oral	75 Mg, Bid		Not Reported
	Tecta			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	2 Df, Qd		Not Reported
	Gold			C	Unknown	Unk		Not Reported
	Voltaren Sr			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	15020708	EXPEDITED (15-DAY)		OT	US-DRREDDYS-USA/USA/18/0100319		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Retinal Toxicity; Toxicity To Various Agents	Docetaxel			S	Unknown	21-Day Cycles		Not Reported
	Anastrozole			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown	21-Day Cycles		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	15622445	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557344-00		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Humira			S	Subcutaneous			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Apo Sulfasalazine			S	Unknown			Not Reported
	Apo Leflunomida			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Used Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Hydroxychloroquine	S	Unknown		Not Reported
Infliximab	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Sulfasalazine	S	Unknown	Enteric Coated	Not Reported
Abatacept	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Adalimumab	S	Subcutaneous		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Leflunomide	S	Unknown		Not Reported
Certolizumab Pegol	S	Subcutaneous		Not Reported
Azathioprine	C	Unknown		Not Reported
Ciclosporin	C	Unknown		Not Reported
Minocycline	C			Not Reported
Penicillamine	C	Unknown		Not Reported
Prednisone	C			Not Reported
Tocilizumab	C			Not Reported
Actemra	C			Not Reported
Prednisolone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	15657201	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20181128756		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported

Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Cimzia	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Plaquenil /00072602/	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Arava	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	15839308	EXPEDITED (15-DAY)		CA, HO, OT	DE-JNJFOC-20190118228			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Foetal Exposure During Pregnancy; Hospitalisation; Premature Baby; Small For Dates Baby	Infliximab, Recombinant			S	Transplacental			Janssen
	Etanercept			S	Transplacental			Not Reported
	Adalimumab			S	Transplacental			Not Reported
	Certolizumab			S	Transplacental			Not Reported
	Anakinra			S	Transplacental			Not Reported
	Methotrexate			S	Transplacental			Not Reported
	Leflunomide			S	Transplacental			Not Reported
	Abatacept			S	Transplacental			Not Reported
	Tocilizumab			S	Transplacental			Not Reported
	Azathioprine			S	Transplacental			Not Reported
	Sulfasalazine			S	Transplacental			Not Reported

	Ciclosporin	S	Transplacental	Not Reported
	Hydroxychloroquine	S	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	15839309	EXPEDITED (15-DAY)		OT	DE-JNJFOC-20190118229			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Complication Of Pregnancy; Ectopic Pregnancy; Foetal Death; Gestational Diabetes; Gestational Hypertension; Haemorrhage; Hip Arthroplasty; Paternal Exposure During Pregnancy; Pre-Eclampsia; Premature Delivery	Infliximab, Recombinant			S	Intravenous (not otherwise specified)			Janssen
	Etanercept			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Certolizumab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	16651301	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202723			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Leflunomide			S		20 Mg, Qw		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S		15 Mg, Qw Solution		Not Reported

Methotrexate	S		20 Mg, Qw	Not Reported
Actemra	S		Unk	Not Reported
Enbrel	S		25 Mg, Qow	Not Reported
Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
Orencia	S		Unk	Not Reported
Orencia	S		125 Mg	Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Mg, Q6w	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Q6w	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	C		Unk	Not Reported
Wellbutrin	C		Unk	Not Reported
Xeljanz	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17114842	EXPEDITED (15-DAY)		OT	DE-TORRENT-00015319			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Ambrisentan			S	Unknown	1 Dosage Form, Qd		Unknown
	Apixaban			S		2.5 Milligram, Bid		Unknown
	Eliquis			S	Unknown	1 Df, Bid (1-0-1)		Unknown
	Lyrica			S	Unknown	100 Milligram, Tid Capsule, Hard		Unknown
	Omeprazole			S	Oral	1 Df,2x/Day (1-0 -1)		Not Reported
	Pregabalin			S	Unknown	1 Df, Tid, 3x/Day (11-1)		Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1-0-1)		Unknown
	Ramipril			S	Oral	1 Df, Bid, 2x/Day (1-0-1)		Not Reported

	Roactemra	S	Subcutaneous	162 Mg, Qw Pre-Filled Syringe	Unknown
	Sildenafil	S	Unknown	60 Milligram, Daily Dose	Not Reported
	Spasmolyt	S	Unknown	1 Df, 15 (Unit Unspecified), Qd (1-0-0)	Unknown
	Volibris	S	Oral	30 Milligram, Qd	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17216520	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-107050		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Once A Day		Not Reported
	Orencia			S	Intravenous (not	Unk		Not Reported

			otherwise specified)		
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram	Not Reported
	Sulfathalidine	S	Unknown	Unk	Not Reported
	Diclofenac	C	Unknown	Unk	Not Reported
	Salazopyrin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17386415	EXPEDITED (15-DAY)		OT	GR-EMD SERONO-E2B_90074536		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Metformin			S	Unknown	Unk		Not Reported
	Thyroxin			S	Unknown	Unk		Not Reported
	Thyroxin			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Ramipril			S	Unknown	Unk		Not Reported
	Exemestane			S	Unknown	Unk		Not Reported

	Lansoprazole		S	Unknown	Unk	Not Reported
	Dicumarol		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17402570	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542912			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17403255	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016019500			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal	Certolizumab Pegol Ra			S	Subcutaneous	400 Mg, Ev 2 Weeks(Qow)		Not Reported
	Certolizumab Pegol Ra			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Not Reported
	Enbrel			S		Unk		Not Reported

Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Tuberculin Test Positive	Enbrel		S		50 Milligram	Not Reported
	Enbrel		S		50 Milligram	Not Reported
	Enbrel		S		50 Milligram	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Humira		S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate		S		5 Milligram	Not Reported
	Leflunomide		S	Oral	10 Milligram	Not Reported
	Leflunomide		S		Unk	Not Reported
	Methotrexate		S		5 Milligram Solution	Not Reported
	Orencia		S		750 Milligram	Not Reported
	Orencia		S		750 Milligram	Not Reported
	Xeljanz		S	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
	Prednisone		C		50 Milligram, Once Daily (Qd)	Not Reported
	Isoniazid		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17411075	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-03838		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anti-Neutrophil Cytoplasmic Antibody Positive Vasculitis; Arthralgia; Chest Pain; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Hypersensitivity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain;	Infliximab			S	Unknown	Unknown		Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Gold			S	Intramuscular	Unknown		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported

Proteinuria; Rheumatoid Arthritis; Treatment Failure; Vasculitis	Methotrexate	S	Subcutaneous	Unknown	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Penicillamine	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Xeljanz	S	Unknown	Unknown	Not Reported
	Azathioprine	S	Oral		Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Unknown	Unknown	Not Reported
	Azathioprine Sodium	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Cyclophosphamide	C	Intravenous (not otherwise specified)	Unknown	Not Reported
	Docusate Sodium	C	Oral		Not Reported
	Elavil	C	Unknown	Unknown	Not Reported
	Prednisone	C	Oral		Not Reported
	Sulfasalazine	C	Oral		Not Reported
	Sulfasalazine	C	Unknown	Unknown	Not Reported
	Tobramycin	C	Unknown		Not Reported
	Doxycycline	C	Oral	Unknown	Not Reported
	Xeljanz	C	Unknown	Unknown	Not Reported

	Elavil		C	Unknown	Unknown	Not Reported
	Wellbutrin		C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17535019	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1196886		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Hepatic Steatosis	Hydroxychloroquine			S	Unknown			Teva
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17583365	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025908		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Subcutaneous	750 Milligram, Qwk		Bristol Myers Squibb
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Parenteral	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous drip	2000 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	50 Milligram, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17623465	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200342100			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17628959	EXPEDITED (15-DAY)		OT	DE-ADVANZ PHARMA-202003002234			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Hallucination; Headache; Nausea	Hydroxychloroquine			S	Unknown	1 Peice Daily, Film Coated Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17656152	EXPEDITED (15-DAY)		CA, OT	FR-SA-2020SA091764			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amniotic Fluid Volume Increased; Foetal Exposure During Pregnancy; Foetal Growth Restriction; Premature Baby	Lovenox			S	Transplacental	1 Df, Qd		Sanofi
	Lovenox			S	Transplacental	Unk		Sanofi
	Plaquenil			S	Transplacental	400 Mg, Qd		Sanofi
	Plaquenil			S	Transplacental	Unk		Sanofi
	Aspegic (Acetylsalicylate Lysine)			S	Transplacental	1 Df, Qd		Not Reported
	Aspegic (Acetylsalicylate Lysine)			S	Transplacental	Unk		Not Reported

Econazole Nitrate	S	Transplacental	300 Mg, Qd		Not Reported
Cortancyl	S	Transplacental	1 Df, Qd		Not Reported
Cortancyl	S	Transplacental	Unk		Not Reported
Imurel [Azathioprine]	S	Transplacental	150 Mg, Qd		Not Reported
Imurel [Azathioprine]	S	Transplacental	Unk		Not Reported
Econazole	C	Transplacental	300 Mg, Qd		Not Reported
Econazole	C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678020	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030940		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Adalimumab			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	22.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Parenteral	25 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk, Qwk		Not Reported

Sulfasalazine	S	Unknown	Unk		Not Reported
Azathioprine	C	Unknown	Unk Unk, Qd		Not Reported
Ciclosporin	C	Unknown	Unk		Not Reported
Minocycline	C	Unknown	Unk		Not Reported
Penicillamine	C	Unknown	Unk		Not Reported
Prednisolone	C	Unknown	6 Milligram, Bid		Not Reported
Tocilizumab	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678220	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020016060			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Cimzia			S	Subcutaneous	Solution		Not Reported
	Actemra			S				Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Once Daily (Qd)		Not Reported
	Methotrexate			S	Oral	20 Milligram, Weekly (Qw)		Not Reported
	Orencia			S				Not Reported
	Prednisone			C	Oral			Not Reported
	Leflunomide			C				Not Reported
	Folic Acid			C	Oral	5 Milligram		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678298	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-244196		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Herpes Zoster Disseminated	Hydroxychloroquine		S	Unknown	200 Milligram, Bid, Daily	Sun
	Prednisone		S	Unknown	5 Milligram, Daily	Mutual

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678709	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020016085		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dry Skin; Fatigue; Pyrexia; Rash; Weight Decreased	Cimzia			S	Subcutaneous	200 Milligram, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678744	EXPEDITED (15-DAY)		HO, LT	FR-TEVA-2020-FR-1224307		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Extrasystoles; Ventricular Tachycardia	Azithromycine Dihydratee			S	Oral	500 Mg D1 Then 250 Mg Per Day		Not Reported
	Plaquenil			S	Oral	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678760	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1777			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Red Blood Cell Sedimentation Rate Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold/Hyoscyamus Niger/Onopordum			S	Unknown			Not Reported

	Acanthium/Primula Veris [Homeopathic]			
	Etanercept	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678761	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1763			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678767	EXPEDITED (15-DAY)		HO	ES-ABBVIE-20K-144-3367094-00		80 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Anuria	Kaletra			S	Oral			Not Reported
	Kaletra			S	Oral			Not Reported
	Dolquine			S	Unknown			Not Reported
	Dolquine			S	Unknown			Not Reported
	Metformina			C	Oral			Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Acovil			C	Oral			Not Reported
	Ganfort			C	Ophthalmic			Not Reported
	Pantoprazol			C	Oral			Not Reported
	Paracetamol			C	Oral			Not Reported
	Simvastatina			C	Oral			Not Reported
	Tramadol + Paracetamol			C	Oral			Not Reported

	Ceftriaxona			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678845	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2020-018482		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pruritus; Rash Maculo-Papular	Repaglinide			S	Oral	Unk		Aurobindo
	Plaquenil			S	Oral	200 Milligram, Once A Day		Not Reported
	Cortancyl			S	Oral	20 Milligram, Once A Day (10-20?G)		Not Reported
	Coversyl			S	Intracardiac	Unk		Not Reported
	Coversyl			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678871	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004002655			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Upper Respiratory Tract Infection	Hydroxychloroquine			S				Concordia
	Bactrim			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678919	EXPEDITED (15-DAY)		DE, OT	FR-ADVANZ PHARMA-202004002835			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Renal Impairment; Septic Shock	Hydroxychloroquine			S		400 Mg, Qd (Film-Coated Tablet)		Concordia
	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17679113	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202003002035			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Hydroxychloroquine	S	Unk	Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17679121	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202003002037			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S	Unk			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17679615	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020156142			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; General Physical Health Deterioration; Mobility Decreased; Musculoskeletal Pain; Nervousness; Pain; Pain In Extremity	Enbrel			S	Unknown			Pfizer
	Methotrexate Sodium			S	Subcutaneous			Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Ciclosporin			S	Unknown			Not Reported
	Diclofenac Sodium			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17679788	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA097024		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Hydroxychloroquine Sulfate			S		2 Df, Qd (Dose: 200mg)		Sanofi
	Cefazolin			S		Unk		Not Reported
	Leflunomide			S	Oral	10.0 Mg		Sanofi
	Methotrexate			S	Subcutaneous	25.0 Mg, Qw		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk (Powder For Solution Intravenous)		Not Reported

Cimzia	S	Subcutaneous	Unk (Solution Subcutaneous)		Not Reported
Rituximab	S		Unk		Not Reported
Enbrel	S		Unk		Not Reported
Orencia	S		Unk		Not Reported
Humira	S	Subcutaneous	Unk (Solution Subcutaneous)		Not Reported
Arava	C		Unk		Not Reported
Viread	C		Unk		Not Reported
Naproxen	C		2 Df, Qd (Dose: 500 Mg)		Not Reported
Xeljanz	C	Oral	2 Df, Qd (Dose: 5.0 Mg)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17679789	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA096908		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Liver Injury; Loss Of Personal Independence In Daily Activities; Neck Pain; Nodule; Pain; Pain In Extremity; Swelling	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Actemra			S				Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17679976	EXPEDITED (15-DAY)		HO, OT	DE-SANOFI-AVENTIS-2012SA019610		31 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epidermal Necrosis; Lip Disorder; Pigmentation Disorder; Skin Lesion; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Cyclophosphamide			S	Unknown	Unk Unk,Unk		Not Reported
	Prednisone			S	Unknown	Unk Unk,Unk		Not Reported
	Chloroquine (Salt Not Specified)			S	Unknown	Unk Unk,Unk		Sanofi
	Sulfamethoxazole/Trimethoprim			S	Unknown	Unk Unk,Unk		Not Reported

Prednisolone	S	Unknown	Unk Unk,Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk Unk,Unk		Sanofi
Leflunomide	S	Unknown	Unk Unk,Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680086	EXPEDITED (15-DAY)		DE, OT	FR-SGP-000004		59 YR	Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Mesenteric Vein Thrombosis; Multiple Organ Dysfunction Syndrome; Product Use In Unapproved Indication; Septic Shock	Methylprednisolone			S	Unknown			Sungen Pharma
	Methylprednisolone			S	Intravenous (not otherwise specified)			Sungen Pharma
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown	0.6 G/M²		Not Reported
	Cyclophosphamide			S	Unknown	0.6 G/M²		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680375	NON-EXPEDITED			US-APPCO PHARMA LLC-2082959			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Musculoskeletal Stiffness	Hydroxychloroquine Sulfate			S				Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680511	NON-EXPEDITED			US-APPCO PHARMA LLC-2082963			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680526	EXPEDITED (15-DAY)		DS, OT	CA-SAMSUNG BIOEPIS-SB-2020-13065		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Musculoskeletal Pain; Off Label Use; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Arava			S	Oral			Not Reported
	Ascorbic Acid			S	Unknown	Unknown		Not Reported
	Atenolol			S	Unknown			Not Reported
	Co Atenolol			S	Unknown			Not Reported
	Co Atenolol			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Ferrous Fumarate			S	Unknown	Unknown		Not Reported
	Ferrous Fumarate;Folic Acid			S	Unknown	Unknown		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral	Unknown	Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Naprosyn [Naproxen Sodium]	S	Oral		Not Reported
Naprosyn [Naproxen Sodium]	S	Oral		Not Reported
Naprosyn [Naproxen Sodium]	S	Oral		Not Reported
Naprosyne	S	Oral		Not Reported
Naprosyne	S	Oral		Not Reported
Naprosyne	S	Oral		Not Reported
Naproxen	S	Oral		Not Reported
Naproxen	S	Oral		Not Reported
Naproxen	S	Oral		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Palafer	S	Unknown	Unknown	Not Reported
Palafer Cf	S	Unknown	Unknown	Not Reported
Pantoloc [Pantoprazole Sodium Sesquihydrate]	S	Unknown		Not Reported
Pantoprazole	S	Unknown		Not Reported
Pantoprazole Sodium	S	Unknown		Not Reported
Pantoprazole Sodium Anhydrous	S	Unknown		Not Reported

Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Remicade	S	Unknown	Unknown		Not Reported
Sulfasalazine	S	Oral			Not Reported
Sulfasalazine	S	Oral			Not Reported
Teva Pantoprazole	S	Unknown			Not Reported
Vitamin C [Ascorbic Acid]	S	Unknown	Unknown		Not Reported
Celebrex	C	Oral			Not Reported
Celecoxib	C	Oral			Not Reported
Prednisone	C	Unknown	Intracardiac		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680759	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004003661			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Disorder	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680864	EXPEDITED (15-DAY)		OT	NVSC2020CA096830		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Treatment Failure	Cyclosporine			S	Unknown			Novartis
	Neoral			S	Oral			Novartis
	Hydroxychloroquine Sulfate			S	Oral	20 Mg		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported

Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
Remicade	S	Unknown	3 Mg/Kg		Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw		Not Reported
Orencia	S	Subcutaneous	125 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680902	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1224376		46 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Milligram Daily; 500 Mg Day		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily; 400 Mg Day		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 Gram Daily; 2 Gr Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680961	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099395			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Prednisone			S				Not Reported
	Actemra			S				Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680984	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099621			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatotoxicity; Rash	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680985	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100529		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Hydroxychloroquine Sulfate			S				Sanofi
	Paracetamol			S				Not Reported
	Arava			S		200 Mg, Qd		Sanofi
	Meloxicam			S				Not Reported
	Methotrexate			S				Not Reported
	Prednisone			S		5 Mg, Qd		Not Reported
	Sulfasalazine			S				Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680986	EXPEDITED (15-DAY)		OT	CA-SA-2020SA098964			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Urinary Tract Obstruction	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Qd		Sanofi
	Leflunomide			S		10 Mg, 2 Every 1 Week		Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported

Azathioprine Sodium	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680987	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099339		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Hand Deformity; Headache; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S		25 Mg, Qd		Not Reported
	Hydroxychloroquine			S				Sanofi
	Sulfasalazine			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680988	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099287		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatic Disorder	Hydroxychloroquine Sulfate			S				Sanofi
	Sulfasalazine			S	Oral			Not Reported
	Arava			S				Sanofi
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Mg		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Cymbalta			C				Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Hydromorphone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680991	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099390			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mood Altered	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi
	Leflunomide			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680992	EXPEDITED (15-DAY)		HO	CA-SA-2020SA099085			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Dehydration; Drug Ineffective	Plaquenil			S				Sanofi
	Methotrexate			S				Not Reported
	Prednisone			S				Not Reported
	Leflunomide			S		Unk		Sanofi
	Azathioprine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680993	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099325			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome;	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Arava			S	Unknown	Unk		Sanofi
	Celecoxib			S	Oral	200 Mg, Bid		Not Reported

Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Orencia	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680994	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100515			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Sulfasalazine			S	Oral	2000 Mg		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Methotrexate			C	Unknown	Unk Unk, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17681009	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099110			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gout; Pneumonia	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Metformin Hydrochloride			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Sanofi
	Colchicine			S	Unknown			Not Reported
	Sitagliptin			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17681011	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099608		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Rash; Treatment Failure; Urticaria	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Sanofi
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17681360	EXPEDITED (15-DAY)		OT	NVSC2020CA102910			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Psoriatic Arthropathy	Cosentyx	S	Unknown	Unk	Novartis
	Cimzia	S	Subcutaneous	Single Use Prefilled Syringe	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Otezla	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelera	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17681818	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-019820		73 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Haemorrhage; Hepatitis Acute	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Ertapenem			S	Intravenous (not otherwise specified)	1 Gram, Once A Day		Aurobindo
	Piperacillin+Tazobactam 4/0.5g Powderforsolutionforinfusion			S	Intravenous (not otherwise specified)	Unk Unk, Once A Day		Aurobindo
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17681820	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-019814		54 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Hepatitis	Azithromycin	S	Oral	500 Milligram, Once A Day	Aurobindo
	Azithromycin	S			Aurobindo
	Ceftriaxone	S	Intravenous (not otherwise specified)	2 Gram, Once A Day	Not Reported
	Ceftriaxone	S			Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram, Two Times A Day	Not Reported
	Hydroxychloroquine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17681821	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-019810		52 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis Cholestatic	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S				Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported
	Ceftriaxone			S				Not Reported
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17685294	DIRECT					52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Dyspnoea; Heart Rate Irregular; Palpitations; Pneumonia	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	11595241	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1641772		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bronchitis; Condition Aggravated; Cystitis; Cystitis; Diarrhoea; Dizziness; Nausea; Pain; Pneumonia; Sensitivity To Weather Change; Swelling; Urinary Tract Infection	Esbriet		S	Oral		Not Reported
	Esbriet		S	Oral		Not Reported
	Esbriet		S	Unknown		Not Reported
	Esbriet		S	Unknown	Dose Increased To 9 Capsules A Day, Every 1 Day	Not Reported
	Xeljanz		S	Oral		Not Reported
	Xeljanz		S	Oral		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Cephalexin [Cefalexin]		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Prednisone		C	Unknown	Therapy Duration: 2 Years	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	15292197	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-AUROBINDO-AUR-APL-2018-041851			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Ezetimibe Tablets			S	Transplacental	From Gestational Week 0-14		Aurobindo
	Pantoprazole			S	Transplacental	40 Milligram, Once A Day		Aurobindo
	Acetylsalicylic Acid			S	Transplacental	100 Milligram, Once A Day		Not Reported
	Ramipril			S	Transplacental	20 Milligram, Once A Day, From Gestational Week 0-113+6		Aurobindo
	Simvastatin Film-Coated Tablet			S	Transplacental	From Gestational Week 0-14		Aurobindo
	Aspirin			S	Transplacental	100 Milligram, Once A Day (From Gestational Week 0-14)		Not Reported
	Aspirin			S				Not Reported
	Aliskiren			S	Transplacental	300 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S	Transplacental	400 Milligram, Once A Day		Not Reported

Metamizole	S	Transplacental	From Gestational Week 0-14	Not Reported
Nicotine	S	Transplacental	From Gestational Week 0-14	Not Reported
Prednisolone	S	Transplacental	10 Milligram, Two Times A Day From Gestational Week 0-14	Not Reported
Xarelto	S	Transplacental	From Gestational Week 0-5	Not Reported
Salbutamol	S	Transplacental	Unk, Once A Day,From Gestational Week 0-14	Not Reported
Tacrolimus	S	Transplacental	6 Milligram, Once A Day	Not Reported
Tacrolimus	S			Not Reported
Torasemide	S	Transplacental	100 Milligram, Once A Day	Not Reported
Heparin	S	Transplacental	Unk	Not Reported
Clexane	S	Transplacental	From Gestational Week 0-14	Not Reported
Clexane	S	Transplacental	200 Milligram, Once A Day	Not Reported
Dalteparin	S	Transplacental	Unk	Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported
Novaminsulfon	S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5	Not Reported
Mifegyne	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
Cytotec	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
Cyclophosphamide	C	Transplacental	3000 [Mg Cumulative]; Preconceptional	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	17682209	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-019426		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Inipomp			C	Unknown	Unk		Not Reported
	Rovamycine			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Xarelto			C	Oral	Unk		Not Reported
	Diffu K			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	17682256	EXPEDITED (15-DAY)		HO, OT	SE-AUROBINDO-AUR-APL-2020-018861		16 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Fatigue; Intentional Overdose; Intentional Self-Injury; Somnolence; Tachycardia	Sertraline			S	Oral	750 Milligram		Aurobindo
	Prednisolone			S	Oral	10-15st.		Not Reported
	Plaquenil			S	Oral	10-15 St.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	17682362	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004003499			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Promyelocytic Leukaemia; Neutropenia; Off Label Use; Thrombocytopenia	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Immunoglobulin I.V			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	17682415	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2020-			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	17682502	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223766			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Morphine Hydrochloride			S	Unknown			Actavis
	Azathioprine			S	Oral			Not Reported
	Bisoprolol Fumarate			S	Unknown			Duramed

	Methotrexate	S	Unknown	Barr
	Pantoprazole	S	Unknown	Teva
	Prednisone	S	Unknown	Actavis
	Zopiclone	S	Unknown	Not Reported
	Cefixime	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Nifedipine	S	Unknown	Not Reported
	Rivotril	S	Unknown	Not Reported
	Zantac	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	17682516	EXPEDITED (15-DAY)		DE, OT	BR-ADVANZ PHARMA-202004002764			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	17682522	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223780			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Morphine Hydrochloride			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Duramed
	Methotrexate			S	Unknown			Barr
	Pantoprazole			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Zopiclone			S	Unknown			Not Reported
	Cefixime			S	Unknown			Not Reported

	Imuran	S	Oral	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Nifedipine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rivotril	S	Unknown	Not Reported
	Zantac	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	17682567	EXPEDITED (15-DAY)		OT	RO-ADVANZ PHARMA-202004003329			Unknown	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	1 Dosage Form, Qd		Concordia
	Euthyrox			S	Unknown	125 Ug, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	17682578	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004002839			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Infection; Joint Injury	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	13165412	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005507		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram		Not Reported

Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
	Methotrexate	S	Unknown	15 Milligram	Not Reported
	Methotrexate	S	Unknown	150 Milligram	Not Reported
	Methotrexate Sodium	S	Unknown	15 Milligram	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	13852964	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070668		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fall; Fatigue; Femur Fracture; Hepatic Enzyme Increased; Infection; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Osteoporosis; Pain; Rash; Synovitis	Orencia			S	Unknown	Unk Unk, Qmo		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate [Methotrexate Sodium]			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Oral	500 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	2 Gram		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	200 Mg, Bid		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	400 Unk	Not Reported
	Naproxen	C	Unknown	Unk	Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Arava	C	Oral	20 Milligram, Qd	Not Reported
	Risedronate	C	Oral	35 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	15751693	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044237		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Drug Intolerance; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Prednisone			S	Unknown	50 Milligram		Not Reported
	Prednisone			S	Oral	3 Mg, Qd		Not Reported
	Prednisone			S	Oral	25 Milligram, Qd		Not Reported
	Prednisone			S	Oral	50 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Bid		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	400 Milligram, Qd		Not Reported
	Apo-Prednisone			S	Unknown	50 Milligram		Not Reported

Treatment Failure; Unevaluable Event; Vomiting	Apo-Prednisone	S	Unknown	25 Milligram, Qd	Not Reported
	Apo-Prednisone	S	Oral	3 Milligram, Qd	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Indocid [Indometacin]	S	Unknown	Unk	Not Reported
	Indometacin	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Milligram, Qd	Not Reported
	Gold (198 Au) Colloidal	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram, Qwk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Arava	S	Unknown	20 Milligram, Qd	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Cymbalta	C	Unknown	30 Milligram, Qd	Not Reported
	Folic Acid Aventis	C	Oral	Unk Unk, Qwk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	17563464	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022239		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height	Orencia			S	Intravenous (not	250 Milligram		Bristol Myers Squibb

Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting				otherwise specified)		
	Actemra		S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
	Actemra		S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
	Anakinra		S	Unknown	50 Milligram	Not Reported
	Anakinra		S	Subcutaneous	50 Milligram, Qd	Not Reported
	Enbrel		S	Unknown	12.5 Milligram, Qwk	Not Reported
	Enbrel		S	Unknown	1.5 Milligram, Qwk	Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Oral	50 Milligram	Not Reported
	Infliximab		S	Intravenous (not otherwise specified)	3 Milligram, Qwk	Not Reported
	Methotrexate		S	Subcutaneous	15 Milligram/Sq. Meter	Not Reported
	Naproxen		S	Unknown		Not Reported
	Prednisone		S	Unknown	Unk	Not Reported
	Prednisone		S	Oral	1.3 Milligram, Bid	Not Reported
	Sulfasalazine		S	Oral	250 Milligram, Qd	Not Reported
	Triamcinolone		S	Other	Unk	Not Reported
	Intravenous Immunoglobulin		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Triamcinolone Hexacetonide		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	17682710	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1223867		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective;	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Indometacin			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Oral	25 Milligram Daily;		Actavis

Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Methotrexate	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Cymbalta	C	Oral	30 Milligram Daily;	Not Reported
	Folic Acid	C	Oral		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	17682746	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-018681			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported

	Methotrexate	S	Intra-arterial	25 Milligram, Once A Day	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	1 Gram, Two Times A Day	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	17682764	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-12491			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Blood Iron Abnormal; Condition Aggravated; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Pain; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Decreased;	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported

Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Azathioprine	S	Unknown	Unknown	Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown		Not Reported
	Certolizumab Pegol	S	Unknown		Not Reported
	Certolizumab Pegol	S	Subcutaneous		Not Reported
	Ciclosporin	S	Oral	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Solution, Single Use Pre-Filled Syringe	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Gold	S	Unknown	Unknown	Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution	Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Lyrica	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Unknown	Not Reported
	Pregabalin	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown	Unknown	Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Simponi	S	Subcutaneous	Unknown. Solution	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous	Unknown	Not Reported
	Folic Acid	C	Unknown		Not Reported
	Piroxicam	C	Unknown	Unknown	Not Reported
	Prednisone	C	Oral	Unknown	Not Reported
	Tofacitinib Citrate	C	Unknown	Unknown	Not Reported
	Xeljanz	C	Oral		Not Reported
	Leflunomide	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	17682792	EXPEDITED (15-DAY)		HO, LT, OT	FR-AUROBINDO-AUR-APL-2020-019423		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Extrasystoles; Ventricular Tachycardia	Azithromycin			S	Oral	500 Mg D1 Then 250 Mg Per Day		Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	17682818	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030938			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Hypersensitivity; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Not Reported

Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Q4wk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Anakinra	C	Unknown	Unk	Not Reported
	Ativan	C	Unknown	Unk	Not Reported
	Benadryl [Acrivastine]	C	Unknown	Unk	Not Reported
	Codeine	C	Unknown	Unk	Not Reported
	Darifenacin	C	Unknown	Unk	Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported
	Dexamethasone	C	Unknown	Unk	Not Reported
	Dilaudid	C	Unknown	Unk	Not Reported
	Hydromorphone	C	Unknown	Unk	Not Reported
	Kadian	C	Unknown	Unk	Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Intra-articular	Unk	Not Reported
	Lasix [Furosemide]	C	Unknown	Unk	Not Reported
	Loperamide	C	Unknown	Unk	Not Reported
	Norflex [Orphenadrine Citrate]	C	Unknown	Unk	Not Reported
	Omnaris	C	Unknown	Unk	Not Reported
	Orphenadrine Citrate	C	Unknown	Unk	Not Reported
	Oxyneo	C	Unknown	Unk	Not Reported
	Pantoloc [Pantoprazole]	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Restasis	C	Unknown	Unk	Not Reported
	Rituximab	C	Intravenous drip	Unk	Not Reported

	Synthroid		C	Unknown	Unk	Not Reported
	Trimethoprim		C	Unknown	Unk	Not Reported
	Urispas		C	Unknown	Unk	Not Reported
	Vagifem		C	Vaginal	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	17682829	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031379			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Orencia			S	Endocervical			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	25 Milligram, Qwk		Not Reported
	Arava			S	Unknown	25 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	17682830	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031430		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Enbrel	S	Subcutaneous			Not Reported
	Gold	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Methotrexate	S	Oral			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rosuvastatin	S	Unknown			Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	17682831	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031383			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported

	Enbrel	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	12289723	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-LUPIN PHARMACEUTICALS INC.-2016-01536			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Hydroxychloroquine			S	Transplacental	Unk (From Gestational Week 0-14)		Lupin
	Ramipril			S	Transplacental	20 Milligram, Qd (From Gestational Week 0-113+6)		Lupin
	Simvastatin Tablets			S	Transplacental	Unk (From Gestational Week 0-14)		Lupin
	Ezetimibe			S	Transplacental	Unk		Not Reported
	Ezetimibe			S	Transplacental	Unk (From Gestational Week 0-14)		Not Reported
	Pantoprazole			S	Transplacental	40 Milligram, Qd (0-13.6 Gestational Week)		Not Reported
	Acetylsalicylic Acid			S	Transplacental	100 Milligram, Qd (From Gestational Week 0-14)		Not Reported
	Xarelto			S	Transplacental	Unk (From Gestational Week 0-5)		Not Reported
	Clexane			S	Transplacental	200 Milligram, Qd		Not Reported
	Tacrolimus			S	Transplacental	6 Milligram, Qd (From Gestational Week 0-14)		Not Reported
	Torasemide			S	Transplacental	100 Milligram, Qd		Not Reported
	Salbutamol			S	Transplacental	Unk Unk, Qd ((From Gestational Week 0-14))		Not Reported
	Enoxaparin Sodium			S	Transplacental	Unk (From Gestational Week 0-14)		Not Reported
	Nicotine			S	Transplacental	Unk (From Gestational Week 0-14)		Not Reported
	Prednisolone			S	Transplacental	10 Milligram, Bid (From		Not Reported

				Gestational Week 0-14)	
	Novaminsulfon	S	Transplacental	Unk (Trimester: First; Probably Only In Hospital In Week 5)	Not Reported
	Dalteparin Sodium	S	Transplacental	Unk	Not Reported
	Metamizole	S	Transplacental	Unk (From Gestational Week 0-14)	Not Reported
	Rituximab	S	Transplacental	Unk (Trimester: Preconceptional)	Not Reported
	Heparin Lmw	S	Transplacental	Unk	Not Reported
	Aliskiren	S	Transplacental	300 Milligram, Qd (0-4.6 Gestational Week)	Not Reported
	Heparin	C	Transplacental	Unk	Not Reported
	Cyclophosphamide	C	Transplacental	Unk (3000 [Mg Cumulative]; Preconceptional)	Not Reported
	Mifegyne	C	Transplacental	Unk (13.6 Gestational Week)	Not Reported
	Cytotec	C	Transplacental	Unk (13.6 Gestational Week)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	12769848	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076833			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown			Not Reported

Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	500 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulphate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Oral	Unk, Bid	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Gold	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported

Arava	S	Unknown	Unk	Not Reported
Arava	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
Cannabis Sativa	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Marijuana	S	Unknown	Unk	Not Reported
Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
Oxycodone	S	Unknown	10 Milligram	Not Reported
Oxycodone Hydrochloride	S	Unknown		Not Reported
Xeljanz	S	Oral	Unk, Q12h	Not Reported
Minocycline	S	Unknown	Unk	Not Reported
Ilaris	S	Subcutaneous	Unk	Not Reported
Ilaris	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Unknown		Not Reported
Oxyquinoline Sulfate	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Rituximab;Urelumab	C	Unknown	Unk	Not Reported
Lyrica	C	Oral	Unk	Not Reported
Kineret	C	Unknown	Unk	Not Reported

	Prednisone		C	Unknown	Unk, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	14217957	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP021473			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Alendronate			S	Unknown	Unk		Apotex
	Alendronate			S	Unknown	70 Mg, Q.I.W		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, B.I.Wk. (Duration:944)		Not Reported
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Oral	10 Mg, Q.I.W		Not Reported
	Methotrexate Sodium			S	Unknown	12 Mg, Q.I.W		Not Reported
	Methotrexate Sodium			S	Unknown	10 Mg, Q.I.W		Not Reported
	Methotrexate Sodium			S	Subcutaneous	17.5 Mg, Q.I.W		Not Reported
	Methotrexate Sodium			S	Subcutaneous	15 Mg, Q.I.W		Not Reported
	Methotrexate Sodium			S	Subcutaneous	10 Mg, Q.I.W		Not Reported
	Methotrexate Sodium			S	Unknown	12.5 Mg, Q.I.W		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk (Duration: 366)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Bid		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	680 Mg, One Every 4 Weeks		Not Reported
	Tocilizumab			S	Unknown	360 Mg, Unk		Not Reported

	Actemra	S	Unknown	360 Mg, Q.M.T.		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	10 Mg, Qd		Not Reported
	Ciclosporin	C	Unknown	150 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	15634974	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105454			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Ankylosing Spondylitis; Condition Aggravated; Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Impaired Gastric Emptying; Influenza; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown	2.5 Milligram, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram		Not Reported
	Infliximab			S	Unknown	25 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	15635082	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105542		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cardiac Disorder; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Ilaris			S	Subcutaneous	Unk		Not Reported
	Ilaris			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not	Unk		Not Reported

		otherwise specified)		
Rituxan	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Oxycodone	S	Unknown	10 Milligram	Not Reported
Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Marijuana	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Rituximab	C	Unknown	Unk	Not Reported
Urelumab	C	Unknown	Unk	Not Reported
Lyrica	C	Oral		Not Reported
Prednisone	C	Unknown	Unk Unk, Qd	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Cannabis Sativa	S	Unknown		Not Reported
Xeljanz	S	Oral	Unk, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	15840631	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001079			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspepsia; Joint Swelling; Therapy Partial Responder	Leflunomide	S	Unknown	Barr
	Methotrexate	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	16045300	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020351		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Pain In Extremity; Peripheral	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depo-Medrol			C	Other	80 Milligram Daily;		Not Reported
	Depo-Medrol			C	Other			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	16079806	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05468			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cardiac Disorder; Diarrhoea; Drug Ineffective; Dyspepsia; Headache; Hypercholesterolaemia; Impaired Work Ability; Pain; Therapy Non-Responder	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown, Solution		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Oral	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Aspirin			C	Unknown	Unknown		Not Reported
	Clopidogrel Bisulfate			C	Oral	Unknown		Not Reported
	Ezetrol			C	Oral	Unknown		Not Reported
	Niaspan			C	Unknown	Unknown, Extended Release Tablet		Not Reported
	Nitroglycerin			C	Transdermal	Unknown		Not Reported
	Rosuvastatin Calcium			C	Oral	Unknown		Not Reported
	Tylenol			C	Oral	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	16563279	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-17758		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Product Use In Unapproved Indication; Product Use Issue; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unknown, Solution		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Immune Globulin (Human)			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen Sodium			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Oral			Not Reported

Triamcinolone	S	Unknown	Unknown, Other Route		Not Reported
Naproxen	S	Unknown	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral			Not Reported
Triamcinolone Hexacetonide	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	16936907	EXPEDITED (15-DAY)		CA, OT	DE-BAUSCH-BL-2019-057945		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Hand Malformation; Developmental Hip Dysplasia; Foetal Exposure During Pregnancy; Small For Dates Baby	Prednisolone			S	Transplacental	Maternal Dose: 5mg, Qd (One In One Day)		Not Reported
	Quensyl			S	Transplacental	Maternal Dose: 200 (Mg/D)/Varying Dosage Between 150 And 200 Mg Daily		Not Reported
	Mono-Embolex			C	Transplacental	Maternal Dose: 3000 (Ie/D)		Not Reported
	L-Thyroxin Jod Beta			C	Transplacental	Maternal Dose: 37.5 (Microg/D) / 75(Microg/D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17528005	EXPEDITED (15-DAY)		DS, HO, OT	NVSC2020CA067701		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Grip Strength Decreased; Joint Swelling; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Diclofenac			S	Oral	1 Df		Novartis
	Diclofenac			S	Oral	2 Df, Qd		Novartis
	Diclofenac			S	Oral	75 Mg, Bid		Novartis
	Diclofenac			S	Oral	75 Mg, Bid		Novartis
	Diclofenac			S	Oral			Novartis
	Diclofenac			S	Oral	Unk, Qd		Novartis
	Diclofenac			S	Oral	Unk		Novartis

Pantoprazole	S	Unknown	Unk	Not Reported
Pantoprazole	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	Unk	Not Reported
Lisinopril	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	1 Df, Qw	Not Reported
Voltaren Sr	S	Oral	2 Df, Qd (75 Mg)	Not Reported
Voltaren Sr	S	Oral	Unk	Not Reported
Diclofenac Potassium	S	Oral		Novartis
Cambia	S	Oral	Unk, Qd	Not Reported
Cambia	S	Oral	Unk	Not Reported
Cambia	S	Unknown	75 Mg, Bid	Not Reported
Sulfasalazine	S	Oral	2 Df, Qd (1 Gram)	Not Reported
Sulfasalazine	S	Unknown	1 Df, Qd (500 Mg)	Not Reported
Pantoprazole Magnesium	S	Unknown	Unk	Not Reported
Plaquenil	S	Oral	1 Df, Qd	Not Reported
Synthyroid	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	2 Df, Qd	Not Reported
Gold	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17584672	EXPEDITED (15-DAY)		OT	NVSC2020US083168			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Gastrointestinal Pain; Joint Swelling	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17597328	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009074		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Breast Cancer; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Infection; Joint Swelling; Loss Of Consciousness; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Hydroxychloroquine	S	Unknown	200 Mg, Unk	Apotex
	Hydroxychloroquine	S	Oral	400 Mg, Unk	Apotex
	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Apo-Hydroxyquine	S	Unknown	Unk	Apotex
	Apo-Leflunomide	S	Unknown	20 Mg, Unk	Apotex
	Leflunomide	S	Unknown	10 Mg, Unk	Apotex
	Leflunomide	S	Oral	20 Mg, Unk	Apotex
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	50 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	25 Mg, Qd	Not Reported
	Methotrexate	S	Unknown	15 Mg, Qd	Not Reported
	Methotrexate	S	Endocervical	25 Mg, Qd	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	50 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Meloxicam	C	Unknown	Unk	Not Reported
	Simponi	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17652112	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1218243		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Ascites; Atrioventricular Block First Degree; Cardiac Failure; Cardiomyopathy; Diastolic Dysfunction; Fluid Overload; Left Ventricular Dysfunction; Right Ventricular Dysfunction; Toxicity To Various Agents	Hydroxychloroquine	S	Unknown	Initial Dosage Not Stated; Tit	Teva
	Hydroxychloroquine	S	Unknown	400 Milligram Daily; Rated To 200mg Twice Daily In The First Year	Teva
	Prednisone	C	Unknown		Not Reported
	Rituximab	C	Other		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17675973	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA097041			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Arava			S	Oral	10 Mg, Qd		Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Methotrexate			S	Intramuscular	25 Mg, Qw		Not Reported
	Leflunomide			S	Oral	10 Mg, Qd		Sanofi
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Asa			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Lozide [Gliclazide]			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

	Naproxen	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Ramipril	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17682990	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-12849		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Body Height Decreased; Drug Ineffective; Flushing; Inflammation; Intentional Product Use Issue; Interstitial Lung Disease; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Xeljanz			S	Unknown	Unknown		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Esomeprazole Sodium			C	Unknown	Unknown		Not Reported
	Lumigan Rc			C	Ophthalmic	Unknown		Not Reported
	Lyrica			C	Unknown			Not Reported
	Sulfasalazin			C	Unknown			Not Reported
	Suphedrine [Pseudoephedrine Hydrochloride]			C	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported
	Valsartan			C	Unknown	Unknown		Not Reported
	Wellbutrin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683235	EXPEDITED (15-DAY)		HO	FR-ADVANZ PHARMA-202004003379			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Oxygen Consumption Increased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd (Film-Coated Tablet)		Concordia
	Nicardipine			C		Unk		Not Reported
	Lovenox			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683260	EXPEDITED (15-DAY)		HO	SE-TEVA-2020-SE-1224953		16 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Fatigue; Intentional Overdose; Intentional Self-Injury; Somnolence; Tachycardia	Prednisolone			S	Oral	10-15st.		Actavis
	Sertraline			S	Oral	750 Mg		Not Reported
	Plaquenil			S	Oral	10-15 St.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683384	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584741			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lymphoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Desoximetasone	C	Unknown		Not Reported
	Diclofenac	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683398	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584183			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthma; Drug Ineffective; Encephalitis Viral; Infection; Lung Disorder; Retinal Deposits; Wheezing	Rituxan			S	Intravenous drip			Not Reported
	Cimzia			S	Subcutaneous	Single Use		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683411	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585127		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Ergocalciferol			C				Not Reported
	Folinic Acid			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683443	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031020		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	360 Milligram		Not Reported
	Actemra			S	Unknown	360 Milligram		Not Reported
	Actemra			S	Unknown	360 Milligram, Qmo		Not Reported
	Actemra			S	Unknown	2.68 Milligram, Q4wk		Not Reported
	Alendronate Sodium			S	Unknown	70 Milligram, Qwk		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulphate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	12 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15.0 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram, Q2wk		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	70 Milligram, Qwk		Not Reported

	Methotrexate		S	Unknown	12.5 Milligram, Qwk	Not Reported
	Methotrexate		S	Unknown	12 Milligram, Qwk	Not Reported
	Methotrexate		S	Unknown	10 Milligram, Qwk	Not Reported
	Methotrexate		S	Unknown	12 Milligram, Qwk	Not Reported
	Myochrysine		S	Parenteral	50 Milligram, Qmo	Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	1000 Milligram, Q12h	Not Reported
	Sulfasalazine		S	Unknown	500 Milligram	Not Reported
	Ciclosporin		C	Unknown		Not Reported
	Prednisone		C	Unknown		Not Reported
	Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683489	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585203		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683494	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1805			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Constipation; Drug Hypersensitivity; Drug Ineffective; Rash; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)		S	Unknown	Not Reported
	Codeine		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Arava		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683880	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA101018		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S		15 Mg		Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	400 Mg, Solution		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral	5 Mg		Not Reported
	Prednisone			C				Not Reported
	Aleve			C				Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683881	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100510			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Arava			S	Unknown	200 Mg, Qd		Sanofi
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Acetaminophen			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683909	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100531		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Cough; Disease Progression; Drug Ineffective; Gait Disturbance; Immobile; Malaise	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi
	Arava			S		20 Mg, Qd		Sanofi
	Celecoxib			S				Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Prednisone			S				Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683915	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099405			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Leukopenia; Liver	Hydroxychloroquine Sulfate			S		Unk, Bid		Sanofi
	Actemra			S				Not Reported
	Arava			S		20 Mg, Qd		Sanofi

Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft Tissue Swelling; Synovitis	Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
	Orencia	S			Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Xeljanz	S			Not Reported
	Acetaminophen	C			Not Reported
	Ativan	C			Not Reported
	Anakinra	C		Unk	Not Reported
	Codeine	C			Not Reported
	Darifenacin	C			Not Reported
	Desoximetasone	C			Not Reported
	Dilaudid	C			Not Reported
	Diphenhydramine	C			Not Reported
	Hydromorphone	C			Not Reported
	Kadian	C			Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Intra-articular	Suspension Intra-Articular	Not Reported
	Oxyneo	C			Not Reported
	Synthroid	C			Not Reported
	Urispas	C			Not Reported
	Trimethoprim	C			Not Reported
	Vagifem	C	Vaginal		Not Reported
	Pantoprazole Sodium Anhydrous	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683917	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099622			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Chest Pain; Eye Ulcer; Foot Deformity; Hand Deformity; Headache; Injection Site Reaction	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Kevzara			S	Unknown			Sanofi
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Leflunomide			C		20 Mg, Qd		Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C		3 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683920	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100527		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Visual Impairment	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Methotrexate			C	Subcutaneous	17.5 Mg, Qw		Not Reported
	Methotrexate			C	Subcutaneous	15 Mg, Qw		Not Reported
	Sulfasalazine			C	Oral	1 G, Qd		Not Reported
	Xeljanz			C		5 Mg, Qd (2 Every 1 Days)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683921	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100715			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Hydroxychloroquine Sulfate			S	Oral			Sanofi
	Leflunomide			S	Oral			Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Xeljanz		C	Oral	5 Mg, Q12h				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683933	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100719			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Colectomy; Diarrhoea; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Speech Disorder Developmental; Treatment Failure; Treatment Failure	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Codeine			S				Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Prednisone			S				Not Reported
	Sulfasalazine			S				Not Reported
	Enbrel			S				Not Reported
	Imuran [Azathioprine]			S				Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683934	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100245		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Musculoskeletal Pain; Pain In Extremity; Pancreatic Carcinoma; Peripheral Swelling; Rheumatoid Arthritis; Splenectomy; Swelling; Therapeutic Product Effect Decreased	Plaquenil			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Arava			S		Unk		Sanofi
	Sulfasalazine			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683935	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100641		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Infection; Leukopenia; Neutropenia	Hydroxychloroquine			S				Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Azathioprine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683937	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099415			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Neutropenia	Hydroxychloroquine Sulfate			S		400 Mg, Qd (1 Every 1 Day)		Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Rituximab			S		Unk		Not Reported
	Orencia			S				Not Reported
	Enbrel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683938	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100724			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Plaquenil			S				Sanofi
	Bisoprolol Salt Not Specified			S				Not Reported
	Cefixime			S				Not Reported
	Methotrexate			S				Not Reported
	Morphine Hydrochloride			S				Not Reported
	Nifedipine			S				Not Reported
	Pantoprazole			S				Not Reported
	Prednisone			S				Not Reported
	Clonazepam			S				Not Reported
	Zantac			S				Sanofi
	Zopiclone			S				Not Reported
	Imuran [Azathioprine]			S	Oral	100 Mg		Not Reported

	Infliximab	S	Intravenous (not otherwise specified)	5.0 Mg/Kg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683939	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA100517			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Hydroxychloroquine Sulfate			S		40 Mg		Sanofi
	Leflunomide			S	Unknown			Sanofi
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Mg, Qd		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683954	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585160			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S				Not Reported
	Ciclosporin			S				Not Reported
	Imatinib			S	Unknown			Not Reported
	Imatinib			S				Not Reported

	Imatinib	S		Not Reported
	Imuran [Azathioprine]	S	Unknown	Not Reported
	Imuran [Azathioprine]	S		Not Reported
	Imuran [Azathioprine]	S		Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S		Not Reported
	Prednisone	S		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
	Tacrolimus	S	Unknown	Not Reported
	Tacrolimus	S		Not Reported
	Tacrolimus	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684002	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224352			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684018	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224903		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Leflunomide			S	Unknown			Barr
	Naproxen			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684130	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224385		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abnormal Loss Of Weight; Alopecia; Arthritis; Drug Ineffective; Hepatic Enzyme Abnormal; Myocardial Infarction; Rash	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous	80 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Clopidogrel Bisulfate			C				Not Reported
	Metoprolol			C				Not Reported
	Pantoprazole			C				Not Reported
	Ramipril			C				Not Reported
	Rosuvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684146	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224905		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Sulfasalazine			C	Oral	1 Gram Daily;		Not Reported
	Xeljanz			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684147	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224454			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Feeding Disorder; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Varenicline Tartrate			S	Oral	1 Milligram Daily;		Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C	Unknown	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Rosuvastatin Calcium	C	Unknown	Not Reported
	Tofacitinib Citrate	C	Unknown	Not Reported
	Valtrex	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684161	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584882			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684208	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100329			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical Device Implantation	Hydroxychloroquine	S		200 Mg, Qd	Sanofi
	Arava	S	Oral	20 Mg, Qd	Sanofi
	Actemra	S		200 Mg, Qm	Not Reported
	Enbrel	S			Not Reported
	Folic Acid	S		1 Mg, Qd	Not Reported
	Humira	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684209	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA100717			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Sulfasalazine			S				Not Reported
	Leflunomide			S		20 Mg, Qd		Sanofi
	Acetaminophen			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			C		1 Df, Qw		Not Reported
	Meloxicam			C				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684211	EXPEDITED (15-DAY)		OT	CA-SA-2020SA098991			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Herpes Zoster; Ill-Defined Disorder; Malaise; Pain; Rheumatoid Factor Increased; Therapeutic Response Decreased	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S				Sanofi
	Diclofenac			S				Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Arthrotec			C				Not Reported
	Desoximetasone			C				Not Reported
	Ibuprofen			C				Not Reported
	Naproxen			C				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Oral			Not Reported
	Prednisone			C	Oral	Unk Unk, Qd		Not Reported
	Sulfasalazine			C				Not Reported
	Synthroid			C		Unk Unk, Qd		Not Reported
	Tramadol			C	Oral	Unk Unk, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684214	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100514			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Intestinal Perforation	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Sanofi
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684329	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224395			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Amenorrhoea; Anxiety; Burning Sensation; Drug Ineffective; Hypoaesthesia; Infection; Juvenile Idiopathic Arthritis; Nausea; Neuropathy Peripheral	Leflunomide	S	Oral		Barr
	Leflunomide	S	Oral		Barr
	Leflunomide	S	Oral		Barr
	Methotrexate	S	Unknown		Barr
	Plaquenil	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Celexa [Celecoxib]	C	Oral		Not Reported
	Cholecalciferol	C	Oral		Not Reported
	Ethinyl Estradiol/Norgestimate	C	Oral	1 Dosage Forms Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684330	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223969			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspepsia; Joint Swelling; Therapy Partial Responder	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684454	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223977		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of	Leflunomide			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported

Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Stress	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Acetaminophen	C			Not Reported
	Dequalinium Chloride	C			Not Reported
	Mefenamic Acid	C	Unknown		Not Reported
	Prednisone	C	Oral	10 Milligram Daily;	Not Reported
	Prednisone	C	Oral	10 Milligram Daily;	Not Reported
	Prednisone	C	Oral	6 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684459	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224366		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Rheumatoid Arthritis; Tremor	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Folic Acid	C	Oral	2.5 Milligram Daily;	Not Reported
	Pantoprazole Magnesium	C	Unknown		Not Reported
	Pantoprazole Magnesium	C	Oral	40 Milligram Daily;	Not Reported
	Tenofovir Disoproxil	C	Unknown		Not Reported
	Tenofovir Disoproxil	C	Oral		Not Reported
	Zopiclone	C	Unknown	7.5 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684499	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224831		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depo-Medrol			C	Other	80 Milligram Daily; Suspension Intraarticular		Not Reported
	Diclofenac			C	Unknown			Not Reported

Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Hydroxychloroquine Sulfate	C	Unknown		Not Reported
	Pantoprazole Magnesium	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684526	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1224892		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone Acetate			S	Unknown			Actavis
	Prednisone Acetate			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684531	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1224908			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide	S	Unknown			Barr
	Naproxen	S	Unknown			Teva
	Prednisone	S	Unknown			Actavis
	Actemra	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid	C	Unknown			Not Reported
	Hydroxychloroquine Sulfate	C	Unknown			Not Reported
	Methotrexate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684650	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224216			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Leflunomide			S	Oral			Barr
	Methotrexate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Lyrica			S	Oral	300 Milligram Daily;		Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684658	EXPEDITED (15-DAY)		HO, LT, OT	CA-SA-2020SA100513			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death;	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi

Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Hydroxychloroquine Sulfate	S	Unknown	Unk	Sanofi
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Sanofi
	Leflunomide	S	Unknown	Unk	Sanofi
	Leflunomide	S			Sanofi
	Leflunomide	S	Unknown	Unk	Sanofi
	Leflunomide	S			Sanofi
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S			Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S			Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S			Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Ilaris	S			Not Reported
	Ilaris	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Ilaris	S			Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S			Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported

	Rituximab	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S			Not Reported
	Sulfasalazine	S	Unknown	500 Mg	Not Reported
	Sulfasalazine	S			Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684724	EXPEDITED (15-DAY)		OT	CA-SA-2020SA098969		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Product Complaint; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Allopurinol			S				Not Reported
	Amitriptyline Hydrochloride			S				Not Reported
	Diclofenac Sodium			S	Topical	Solution Topical		Not Reported
	Diclofenac Sodium			S		Unk		Not Reported
	Diclofenac Sodium			S		Unk		Not Reported
	Diclofenac Potassium			S				Not Reported
	Arava			S				Sanofi
	Arava			S		Unk		Sanofi
	Arava			S		Unk, Apo-Leflunomide, Tablet		Sanofi
	Naproxen			S				Not Reported
	Naproxen			S		Unk		Not Reported
	Naproxen			S		Unk, Apo-Naproxen		Not Reported
	Prednisone			S		5 Mg, Apo-Prednisone		Not Reported
	Prednisone			S		Unk		Not Reported
	Prednisone			S		Unk, Winpred		Not Reported
	Celecoxib			S				Not Reported
	Celecoxib			S		Unk		Not Reported

Celecoxib	S		Unk, Capsule	Not Reported
Celecoxib	S		Unk, Capsule	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)		Not Reported
Methotrexate	S	Parenteral	Unk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S		Unk	Not Reported
Misoprostol	S			Not Reported
Pregabalin	S			Not Reported
Sulfasalazine	S			Not Reported
Amitriptyline	S			Not Reported
Amitriptyline With Perphenazine	S			Not Reported
Apo-Azathioprine	S			Not Reported
Azathioprine	S			Not Reported
Diclofenac Sodium And Misoprostol	S			Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
Etanercept	S			Not Reported
Actemra	S			Not Reported
Humira	S	Subcutaneous	40 Mg	Not Reported
Lyrica	S			Not Reported
Nifedipine	S			Not Reported
Orencia	S	Subcutaneous	750 Mg, Qw	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	2000 Mg	Not Reported
Xeljanz	S	Oral	5.0 Mg, Bid	Not Reported
Tofacitinib	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684872	EXPEDITED (15-DAY)		LT	CA-TEVA-2020-CA-1223974		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein	Leflunomide			S	Unknown			Barr

Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Methotrexate	S	Unknown	Barr
	Methotrexate	S		Barr
	Actemra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Rituximab	C	Unknown	Not Reported
	Urelumab	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685014	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA100424		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash; Urticaria	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Actemra			S				Not Reported

Enbrel	S				Not Reported
Humira	S	Subcutaneous	Solution		Not Reported
Atenolol	C	Oral	50 Mg, Qd		Not Reported
Hydrochlorothiazide	C		25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685016	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA100528		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cardiovascular Disorder; Condition Aggravated; Cystitis; Deformity; Depressed Mood; Dermatitis; Drug Ineffective; Encephalitis; Encephalitis Brain Stem; Fall; Fibromyalgia; Immobile; Immune System Disorder; Immunodeficiency; Joint Destruction; Loss Of Personal Independence In Daily Activities; Memory Impairment; Pain; Peripheral Swelling; Psychiatric Symptom; Rheumatoid Arthritis; Rib Fracture; Scar; Seizure; Sepsis; Spinal Deformity; Vomiting	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Bid		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown	14 Mg, Qd		Not Reported
	Arava			S	Unknown			Sanofi
	Celecoxib			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, Qm		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Furosemide			C	Unknown	Unk Unk, Qd		Not Reported
	Hydromorph Contin			C		18 Mg, Tid, Sustained Release		Not Reported
	Dilaudid			C	Unknown	4 Mg, Tid		Not Reported
	Lyrica			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685106	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224477			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Colitis	Leflunomide			S	Unknown			Barr

Ulcerative; Contraindicated Product Administered; Drug Ineffective; Effusion; Rheumatoid Factor Positive; Synovitis	Methotrexate		S	Unknown	Barr
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685109	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224361			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685110	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224214			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Leflunomide			S	Unknown	20 Mg		Barr
	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

	Humira		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Meloxicam		C	Unknown	Not Reported
	Sulfasalazine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685113	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1224210			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Medication Error; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Oral	3 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685114	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224837		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled			S	Unknown			Not Reported

Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Syringe		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate		C	Unknown		Not Reported
	Ergocalciferol		C	Unknown		Not Reported
	Estradiol		C	Unknown		Not Reported
	Estrogel		C	Unknown	1.8 Percent Daily;	Not Reported
	Furosemide		C	Unknown		Not Reported
	Morphine		C	Unknown		Not Reported
	Potassium Chloride		C	Unknown		Not Reported
	Valsartan		C	Unknown		Not Reported
	Xalatan		C	Unknown		Not Reported
	Zingiber Officinale		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685278	EXPEDITED (15-DAY)		LT	CA-SAMSUNG BIOEPIS-SB-2020-13385			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea;	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S				Not Reported
	Apo-Naproxen			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Oral			Not Reported

Obesity; Off Label Use; Product Use In Unapproved Indication; Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous	Unknown, Solution	Not Reported
	Humira		S	Unknown	Unknown	Not Reported
	Hydroxychloroquine		S	Oral	Unknown	Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Methotrexate		S	Unknown	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Orencia		S			Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Triamcinolone		S	Intra-articular	Unknown	Not Reported
	Triamcinolone		S			Not Reported
	Folic Acid		C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685511	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224221		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Elbow Deformity; Headache; Liver Function Test Increased; Rheumatoid Arthritis	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685527	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224426			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685606	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-13343		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective For Unapproved Indication; Hypersensitivity; Incorrect Route Of Product Administration; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous	Unknown		Not Reported
	Methotrexate			S	Oral	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Varicella-Zoster Immune Globulin			S	Subcutaneous	Liquid Intramuscular, Dose: Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685629	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223866		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Tremor	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Tenofovir Disoproxil Fumarate			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Zopiclone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685690	EXPEDITED (15-DAY)		OT	NVSC2020GB104678			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685725	EXPEDITED (15-DAY)		OT	CA-BAXTER-2020BAX008388		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Cough; Drug Intolerance; Dyspnoea; Forced Vital Capacity Decreased; Lung Diffusion Test Decreased; Pulmonary Function Test Decreased; Therapy Non-Responder; Treatment Failure	Procytox (Cyclophosphamide) 2000mg/Vial		S	Unknown	Dosage Form: Not Specified	Baxter
	Mycophenolate Mofetil		S	Unknown	Dosage Form: Not Specified	Not Reported
	Mycophenolate Mofetil		S	Oral		Not Reported
	Mycophenolate Mofetil		S			Not Reported
	Plaquenil		S	Unknown	Dosage Form: Tablet	Not Reported
	Rituxan		S	Unknown	Dosage Form: Solution Intravenous	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Cymbalta		C	Unknown	Dosage Form: Not Specified	Not Reported
	Domperidone		C	Unknown	Dosage Form: Tablet	Not Reported
	Hydroxychloroquine		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685734	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1224445			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Dizziness; Gastrointestinal Disorder; Headache; Hypotension; Joint Noise; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Psoriatic Arthropathy; Rheumatoid Arthritis; Sensitivity To Weather Change; Therapeutic Product Effect Decreased; Vaginal Haemorrhage; Vomiting; Weight Increased	Leflunomide			S	Oral	10 Milligram Daily;		Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Leucovorin			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C				Not Reported
	Calcium Citrate; Magnesium Citrate			C				Not Reported
	Citalopram Hydrobromide			C				Not Reported
	Clobetasol Propionate			C	Topical			Not Reported

	Naproxen	C	Oral	Not Reported
	Pantoprazole Magnesium	C		Not Reported
	Escitalopram Oxalate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685735	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1224422		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Hip Arthroplasty; Infection; Knee Arthroplasty; Seronegative Arthritis; Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685779	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224435			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Desoximetasone	C	Unknown	10 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685786	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223872			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Urinary Tract Obstruction	Azathioprine Sodium			S	Unknown			Not Reported
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685788	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223967			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	4800 Milligram Daily;		Not Reported
	Kevzara			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685791	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224383			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Leflunomide	S	Unknown	Barr
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Prednisone	C		Not Reported
	Cimzia Single-Use Prefilled Syringe	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685813	EXPEDITED (15-DAY)		DE	ES-ASTRAZENECA-2020SE51307		95 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Quetiapine			S	Oral			Zeneca
	Hydroxychloroquine Sulphate			S	Oral			Not Reported
	Levofloxacin			S	Intravenous (not otherwise specified)			Not Reported
	Kaletra			S	Oral	200/50 Mg, 2 Df Daily, 120 Tablets		Not Reported
	Risperidone			S	Oral			Not Reported
	Losartan			C	Oral			Not Reported
	Clindamycin Hydrochloride			C	Intravenous (not otherwise specified)			Not Reported
	Lorazepam			C	Oral			Not Reported

	Furosemide		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685815	EXPEDITED (15-DAY)		DS	CA-SAMSUNG BIOEPIS-SB-2020-12772		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Hand Deformity; Pain; Rheumatoid Arthritis; Swelling; Treatment Failure	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown,		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown,		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral	Unknown		Not Reported
	Acetaminophen/Oxycodone Hydrochloride			C	Unknown	Unknown		Not Reported
	Celebrex			C	Oral	Unknown		Not Reported
	Furosemide			C	Unknown	Unknown		Not Reported
	Morphine			C	Unknown	Unknown		Not Reported
	Oxycodone Terephthalate			C	Unknown	Unknown		Not Reported
	Ramipril			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685895	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224217			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685905	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223975		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate	S	Parenteral	1 Gram Daily;	Not Reported
	Sulfasalazine	S	Unknown	1 Gram Daily;	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Actemra	S	Unknown		Not Reported
	Lyrica	C	Oral		Not Reported
	Prednisone	C	Unknown	15 Milligram Daily;	Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685927	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224413			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Nausea; Neuropathy Peripheral	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Depo-Medrol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685928	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1223947			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism	Leflunomide			S	Unknown			Barr
	Leflunomide			S				Barr
	Methotrexate			S	Intra-arterial			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported

	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Ilaris Single-Use Vial	S	Unknown	Not Reported
	Ilaris Single-Use Vial	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685929	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223955			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Symptom; Alopecia; Arthralgia; Bone Disorder; Cyst; Hand Fracture; Seronegative Arthritis; Urinary Tract Obstruction	Leflunomide			S	Oral			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685981	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224403			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Remicade			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685990	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223963			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Empyema; Musculoskeletal Stiffness; Pain	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Leflunomide			S	Oral	10 Milligram Daily;		Barr
	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17686061	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1223940			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Leflunomide			S	Unknown			Barr
	Leflunomide			S				Barr
	Methotrexate			S	Intra-arterial			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17686242	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2020-13015		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Infliximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Infliximab	S			Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Alendronate	S	Unknown		Not Reported
	Codeine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Xeljanz	C	Unknown	Unknown	Not Reported
	Prednisone	C	Unknown	Unknown	Not Reported
	Ciclosporin	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17686331	EXPEDITED (15-DAY)		OT	NVSC2020CA105008			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Inflammation; Local Reaction; Musculoskeletal Pain; Nausea; Neck Pain; Pain In Extremity; Rash; Syncope; Vomiting	Aclasta			S	Intravenous (not otherwise specified)	Unk		Novartis
	Morphine Sulfate			S	Unknown	Unk		Not Reported
	Codeine Phosphate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plantago Afra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydrochlorothiazide			C	Unknown	Unk		Not Reported
	Lipitor			C	Unknown	10 Mg, Qd		Not Reported
	Methotrexate			C	Subcutaneous	22.5 Mg, Qw		Not Reported
	Folic Acid			C	Unknown	5 Mg		Not Reported
	Ergocalciferol			C	Unknown	2000 Iu, Qd		Not Reported
	Cannabis Sativa			C	Unknown	Unk Unk, Qd		Not Reported
	Calcium Carbonate			C	Unknown	Unk		Not Reported
	Asa			C	Unknown	81 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17686344	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3365681-00		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Back Pain; Chest Pain; Cough; Diarrhoea; Drug Ineffective; Eye Irritation; Headache; Musculoskeletal Pain; Nasopharyngitis; Pleural Effusion; Pyrexia; Retinal Injury; Rhinorrhoea	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17686390	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-032357			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17686431	EXPEDITED (15-DAY)		DS, OT	US-ADVANZ PHARMA-202004003537			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Vision Loss; Macular Degeneration; Maculopathy; Retinal Toxicity; Retinopathy; Vision Blurred	Hydroxychloroquine			S		800 Mg, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17686581	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-018504		21 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hepatitis; Hypocoagulable State; Pancreatitis Acute	Linezolid			S	Intravenous (not otherwise specified)	Unk		Aurobindo
	Ambisome			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported

	Tocilizumab		S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17686584	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018508		63 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S				Aurobindo
	Paracetamol			S	Oral	1 Gram, 3 Times A Day		Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported
	Ceftriaxone			S				Not Reported
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17690121	DIRECT		HO				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral	400mg Bid For 1 Day Then 200bid For 1 Day Bid Po X 1 Day(S)		Not Reported
	Azithromycin			S		500mg Qd X 1 250mg Daily For 3 Days Qd Po X 3 Day(S)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	12913728	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091701			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Drug Ineffective; Drug Intolerance;	Orencia			S	Intravenous (not otherwise specified)	40 Milligram		Bristol Myers Squibb

Hypersensitivity; Hypoaesthesia; Infection; Nausea; Nephrolithiasis; Nerve Injury; Neutropenia; Off Label Use; Osteoarthritis; Pain In Extremity; Paraesthesia; Product Use Issue; Pulmonary Congestion; Synovitis; White Blood Cell Count Decreased	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk, 152.0 Days	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk, 122 Days	Not Reported
	Humira	S	Subcutaneous	40 Milligram, 2 Every One Week	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	Unk, 580.0 Days	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram, 580.0 Days	Not Reported
	Apo-Hydroxyquine	S	Oral	400 Milligram	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Naprosyn E	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	13153195	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005339			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Bone Disorder; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Finger	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported

Deformity; Pain; Peripheral Swelling; Rash; Swelling; Tendon Disorder; Tenosynovitis; Treatment Failure; Urticaria	Enbrel	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Rocuronium	S	Unknown	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown	Unk	Not Reported
	Pencillin	S	Unknown	Unk	Not Reported
	Apo Hydroxyquine	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Penicillin G [Benzylpenicillin Sodium]	S	Unknown	Unk	Not Reported
	Rocuronium Bromide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	13182370	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-17K-028-1856140-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Multiple Fractures; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported
	Aleve			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Naproxen			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Prednisone Teva			S	Oral			Not Reported
	Plaquenil Sulfate			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	13519381	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038159		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Alopecia; Arthropathy; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Glossodynia; Hand Deformity; Nausea; Oedema; Off Label Use; Pain; Pemphigus; Prescribed Overdose; Rheumatoid Arthritis; Synovitis; Systemic Lupus Erythematosus; Vomiting	Orencia			S	Subcutaneous	150 Mg, Qmo		Bristol Myers Squibb
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Qmo		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	25 Milligram		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Celebrex			S	Unknown	200 Milligram		Not Reported
	Naprosyn [Naproxen Sodium]			S	Unknown	500 Mg, Bid		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Folic Acid			S	Unknown	500 Milligram		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported

	Rituximab		S	Unknown	1 Gram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	13850192	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070656			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Nodule; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tenosynovitis; Therapeutic Response Decreased; Tooth Disorder; Tooth Infection; Weight Decreased	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Q4wk,Cyclical		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	10 Mg, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Actonel			C	Unknown	35 Milligram		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Risedronate Sodium			C	Unknown	35 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	15163376	EXPEDITED (15-DAY)		OT	CA-ROCHE-2154400		29 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ill-Defined Disorder; Systemic Inflammatory Response Syndrome; Ulcer; Vasculitis	Mycophenolate Mofetil			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	15418599	EXPEDITED (15-DAY)		OT	DE-JNJFOC-20180917519		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Ciclosporin			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Subcutaneous			Not Reported

Methotrexate	S	Oral			Not Reported
Hydroxychloroquine	S	Oral			Not Reported
Methotrexate Sodium	S	Subcutaneous			Not Reported
Neoral	S	Oral			Not Reported
Neoral	S	Subcutaneous			Not Reported
Apo-Hydroxyquine	S	Unknown			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Oral			Not Reported
Xeljanz	C	Oral			Not Reported
Xeljanz	C	Oral			Not Reported
Xeljanz	C	Oral	2 Ot		Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	15680209	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2574019-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Celecoxib			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celecoxib			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	15702743	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2581224-00		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass Excision; Nodule; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Novo-Rythro			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Marijuana			C				Not Reported
	Risedronate			C	Oral			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Hydroxychloroquine			C	Oral			Not Reported
	Bupropion			C	Unknown			Not Reported
	Cannabis Sativa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	15932044	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2651975-00		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not			Not Reported

Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus				
	Apo-Folic Acid	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S		Not Reported
	Cetirizine Hydrochloride W/Pseudoephedrine	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Golimumab	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported

	Sulfathalidine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	16396768	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2809469-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Off Label Use; Prescribed Underdose; Product Use Issue	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Prednisone	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	16640871	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-070998			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	16724652	EXPEDITED (15-DAY)		HO, OT	PHHY2019CA192974		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder;	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Voltaren			S	Unknown			Novartis
	Voltaren			S				Novartis
	Voltaren			S				Novartis
	Voltaren			S				Novartis
	Diclofenac Potassium			S	Unknown	Unk		Novartis
	Clopidogrel			S	Unknown	Unk		Not Reported
	Clopidogrel			S				Not Reported
	Clopidogrel			S				Not Reported
	Clopidogrel			S				Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported

Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Methotrexate	S			Not Reported
	Vitamin C	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S			Not Reported
	Arava	S			Not Reported
	Arava	S			Not Reported
	Asa	S	Unknown	325 Mg (Delayed Release)	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Gold	S			Not Reported
	Gold	S			Not Reported
	Gold	S			Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Humira	S			Not Reported
	Humira	S			Not Reported
	Motrin	S	Unknown	Unk	Not Reported
	Motrin	S			Not Reported
	Motrin	S			Not Reported
	Motrin	S			Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Naproxen	S			Not Reported
	Naproxen	S			Not Reported
	Naproxen	S			Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S			Not Reported
	Plaquenil	S			Not Reported
	Plaquenil	S			Not Reported
	Tramadol	S	Unknown	Unk	Not Reported
	Apo-Diclofenac	S	Topical		Not Reported
	Aspirin	S	Unknown		Not Reported
	Aspirin	S			Not Reported
	Aspirin	S			Not Reported
	Aspirin	S			Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Ibuprofen	S	Unknown		Not Reported

	Sulfamethoxazole	S	Unknown	Not Reported
	Trimethoprim	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	16841034	EXPEDITED (15-DAY)		OT	GR-BAUSCH-BL-2019-026015		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperparathyroidism Secondary; Osteoporosis; Rib Fracture; Upper Respiratory Tract Infection	Ramipril			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Bausch And Lomb
	Metformin Hydrochloride			S	Unknown			Santarus
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lansoprazole			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Exemestane			S	Unknown			Not Reported
	Thyroxine			S	Oral			Not Reported
	Thyroxine			S	Unknown			Not Reported
	Dicumarol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	16886720	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2946845-00		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Sulfathalidine			S	Oral			Not Reported

Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Cortisone	S	Topical		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown	Powder For Infusion	Not Reported
	Cetirizine	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Methotrexaat	S	Oral		Not Reported
	Plaquenil	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Pre-Filled Syringe	Not Reported
	Arava	S	Oral		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Cetirizine Hydrochloride W/Pseudoephedrine	S	Unknown		Not Reported
	Topicort (Hydrocortisone Acetate)	S	Cutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Prednisone	S	Oral		Not Reported

	Desoximetasone	S	Oral	Not Reported
	Diclofenac	S	Ophthalmic	Not Reported
	Alendronate Sodium	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Golimumab	S	Unknown	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Stelara	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Atasol	C	Unknown	Not Reported
	Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	6965678	EXPEDITED (15-DAY)		OT	DE-RANBAXY-2009RR-23202		42 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Reconstitution Inflammatory Syndrome	Ceftriaxone			S	Unknown	Unk		Not Reported
	Co-Trimoxazole			S	Unknown	Unk		Mutual
	Doxycycline Hydrochloride			S	Unknown	Unk		Sun
	Hydroxycholoroquine Sulphate-Bp			S	Unknown	Unk		Sun
	Streptomycin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17260297	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017687			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Dorzolamide ,Timolol			S	Unknown	1 Df, Bid		Apotex
	Dorzolamide ,Timolol			S	Unknown	Unk Unk, Bid		Apotex
	Ramipril			S	Oral	Unk, Qd		Apotex
	Ramipril			S	Oral	Unk		Apotex
	Actemra			S	Unknown			Not Reported
	Levothyroxine			S	Unknown	1 Df, Unk		Not Reported
	Levothyroxine			S	Unknown	Unk, Qd		Not Reported
	Tylenol /00020001/			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Endocervical	400 Mg, Qd		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Dorzolamide Hydrochloride W/Timolol Maleate			C	Ophthalmic	Unk, Bid		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Levothyroxine			C	Unknown	One Once A Day		Not Reported
	Prednisone			C	Unknown	7 Mg, Qd		Not Reported

Ramipril	C	Unknown	One Once A Day		Not Reported
Tylenol No.2	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17332504	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-004133		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown	Unk, Bid		Not Reported
	Ergocalciferol			C	Unknown	Unk, Qwk		Not Reported
	Estrogel			C	Unknown	0.6 Percent, Tid		Not Reported
	Furosemide			C	Unknown	40 Milligram, Qd		Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown	1500 Milligram, Qd		Not Reported
	Valsartan			C	Unknown	320 Milligram, Qd		Not Reported
	Xalatan			C	Unknown	50 Microgram, Qd		Not Reported
	Zingiber Officinale			C	Unknown	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17517039	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200243785			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Condition Aggravated; Contraindicated Product	Stelara			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not			Janssen

Administered; Drug Ineffective; Drug-Induced Liver Injury; Liver Function Test Increased; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure; Uveitis			otherwise specified)	
	Simponi	S	Subcutaneous	Janssen
	Cimzia	S	Subcutaneous	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Otezla	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Naprosyn /00256201/	S	Unknown	Not Reported
	Piroxicam	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Codeine	C	Unknown	Not Reported
	Codeine	C	Subcutaneous	Not Reported
	Imuran /00001501/	C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17577763	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200329927		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anti-Neutrophil Cytoplasmic Antibody Positive Vasculitis; Arthralgia; Back Injury; Back Pain; Chest Pain; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Hypersensitivity; Inflammation; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Proteinuria; Rheumatoid Arthritis; Swelling; Treatment Failure; Vasculitis	Simponi			S	Subcutaneous			Janssen
	Arava			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Penicillamine			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S				Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			C				Not Reported
	Cyclophosphamide			C				Not Reported
	Docusate Sodium			C				Not Reported
	Doxycycline			C	Oral			Not Reported
	Elavil /00002202/			C	Unknown			Not Reported
	Sulfasalazine			C	Oral			Not Reported
	Tobramycin			C	Intraocular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17579767	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327866		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated	Simponi			S	Subcutaneous			Janssen

Product Administered; Drug Ineffective; Headache; Hepatotoxicity; Insomnia; Joint Swelling; Memory Impairment; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Remicade	S	Intravenous (not otherwise specified)		Janssen
	Actemra	S	Intravenous (not otherwise specified)	8.0 Mg/Kg	Not Reported
	Anakinra	S	Subcutaneous	100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes	Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Methotrexate	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	S	Oral		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Insulin	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17579770	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327863		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain; Constipation; Diarrhoea; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Hypersensitivity; Insomnia; Iodine Allergy; Nausea; Oedema; Off Label Use; Pain; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis; Synovitis; Vomiting	Simponi	S	Subcutaneous	Janssen
	Arava	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Venlafaxine	C	Oral	Not Reported
	Folic Acid	C		Not Reported
	M-Eslon	C	Unknown	Not Reported
	Morphine	C		Not Reported
	Morphine Sulfate	C	Unknown	Not Reported
	Statex	C	Unknown	Not Reported
	Hydrodiuril	C	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported
	Naprosyn /00256201/	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17579772	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327858		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Methotrexate	S	Unknown		Not Reported
	Salazopyrin	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17579773	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327868		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Actonel			S				Not Reported
	Celebrex			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prolia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Minims Prednisolone Sodium Phosphate			S	Ophthalmic	0.5%		Not Reported
	Arava			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

	Cyclobenzaprine	C		Not Reported
	Desoximetasone	C		Not Reported
	Prednisone Acetate	C		Not Reported
	Tylenol /00020001/	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17605649	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332785		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Arthralgia; Arthropathy; Drug Intolerance; Joint Swelling; Knee Arthroplasty; Therapeutic Product Effect Decreased; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17616081	EXPEDITED (15-DAY)		DE, HO	BR-ADVANZ PHARMA-202003002042			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Drug Ineffective; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17623454	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340457		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Decreased; Weight Increased	Simponi	S	Subcutaneous	Janssen
	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Actemra	S	Unknown	Not Reported
	Amlodipine Besilate	S	Oral	Not Reported
	Asacol	S	Unknown	Not Reported
	Diamicron	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gliclazide	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Acetaminophen	C	Oral	Not Reported
	Atacand Plus	C	Unknown	Not Reported
	Bisoprolol Fumarate	C	Unknown	Not Reported
	Depo-Medrol	C	Intra-articular	Not Reported
	Diphenhydramine	C	Oral	Not Reported
	Ebastine	C	Unknown	Not Reported
	Ferrous Gluconate	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
	Rosuvastatin Calcium	C	Unknown	Not Reported

	Tylenol	C	Unknown	Not Reported
	Vitamin D3	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17623463	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200342096		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Malaise; Nausea; Stress	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1.0 Dosage Forms		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Advil /00044201/			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Tylenol /00020001/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17623466	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340460		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Hypertension; Impaired Work Ability; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17623532	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340124		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Off Label Use; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Cyclobenzaprine			C	Oral			Not Reported
	Cyclobenzaprine			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Leflunomide			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone Acetate			C	Unknown			Not Reported
	Tylenol /00020001/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17623533	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340125		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Back Pain; Bursitis; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Dry Mouth; Facet Joint Syndrome; Headache; Inflammation; Joint Range Of Motion Decreased; Joint Swelling;	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Asa			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Lip Dry; Liver Disorder; Lung Disorder; Muscle Spasms; Musculoskeletal Pain; Musculoskeletal Stiffness; Night Sweats; Obesity; Oedema; Oedema Peripheral; Off Label Use; Osteoarthritis; Pain; Pain In Extremity; Paraesthesia; Peripheral Swelling; Peripheral Venous Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatic Fever; Swelling; Synovitis	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported
	Acetaminophen	C		Not Reported
	Ultracet	C		Not Reported
	Calcite D	C	Unknown	Not Reported
	Citalopram	C		Not Reported
	Domperidone	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Gabapentin	C		Not Reported
	Gliclazide	C	Unknown	Not Reported
	Lipitor	C		Not Reported
	Nifedipine	C		Not Reported
	Pantoloc /01263204/	C	Unknown	Not Reported
	Pantoprazole	C		Not Reported
	Risedronate	C	Unknown	Not Reported
	Risedronate Sodium	C	Unknown	Not Reported
	Synthroid	C		Not Reported
	Tylenol /00020001/	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17623537	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340129		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Blood Creatinine Increased; Diarrhoea; Drug Ineffective; Limb Discomfort; Musculoskeletal Discomfort; Off Label Use; Pain; Pharyngeal	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

Oedema; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S		Not Reported
	Penicilline G /00000901/	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17623540	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340132			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17623542	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20200340452		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug Ineffective; Fine Motor Skill Dysfunction; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Musculoskeletal Disorder; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Therapeutic Product Effect Decreased; Treatment Noncompliance	Simponi			S	Subcutaneous			Janssen
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17666231	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029672		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger Deformity; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rocuronium Bromide	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17672252	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200413057		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17681010	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100512			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Sanofi
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Sanofi
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Naproxen			C	Unknown	500 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17686409	EXPEDITED (15-DAY)		OT	CA-TAKEDA-2020TUS018625			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Antinuclear Antibody Positive; Arthralgia; Arthritis; Blister; Dry Mouth; Headache; Hypersensitivity Vasculitis; Hypoaesthesia; Joint Swelling; Leukopenia; Lip	Dexilant			S	Oral	60 Milligram, Qd		Takeda
	Colchicine			S	Unknown	Unk		Takeda
	Estrogel			S	Topical	Unk Unk, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Breo Ellipta			S	Respiratory	Unk		Not Reported

Swelling; Lymphadenopathy; Menorrhagia; Musculoskeletal Stiffness; Myalgia; Nausea; Parotid Gland Enlargement; Peripheral Swelling; Rheumatoid Arthritis; Sjogren'S Syndrome; Systemic Lupus Erythematosus; Vasculitis			(inhalation)			
	Celebrex	S	Unknown	Unk		Not Reported
	Meloxicam	S	Unknown	Unk		Not Reported
	Methotrexate	S	Oral	Unk		Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil /00072602/	S	Unknown	200 Milligram, Bid		Not Reported
	Prednisone	S	Unknown	50 Milligram		Not Reported
	Rituximab	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Ventolin Hfa	S	Respiratory (inhalation)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17686802	EXPEDITED (15-DAY)		OT	JP-LAURUS LABS LIMITED-202000088		41 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Placenta Accreta	Hydroxychloroquine			S	Unknown			Unknown
	Prednisolone			C	Unknown			Not Reported
	Tacrolimus			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17686999	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585020		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Intolerance; Herpes Zoster; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous drip			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)	
	Simponi	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Lyrica	C		Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687219	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-244391			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Nightmare; Product Use In Unapproved Indication; Psychomotor Hyperactivity	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Plaquenil 200 Mg, Comprime Enrobe			S	Oral	600 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687411	EXPEDITED (15-DAY)		OT	DE-TEVA-2020-DE-1224814		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Granuloma Skin; Mycobacterium Marinum Infection	Leflunomide			S	Unknown			Barr
	Prednisolone			S	Unknown	Low-Dose		Actavis
	Prednisolone			S	Unknown			Actavis
	Prednisolone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Teva
	Sulfasalazine			S	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687714	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100422		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Prednisone			S	Oral	5 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, Bid		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	20 Mg, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687715	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100732			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S		200 Mg, Qd		Sanofi
	Methotrexate			S	Oral	25 Mg, Qd		Not Reported
	Arava			S				Sanofi
	Myochrysine			S	Intramuscular	25 Mg, Qw		Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687716	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100909		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Hydroxychloroquine Sulfate			S		100 Mg		Sanofi
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Apo-Azathioprine			S		100 Mg		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocycline			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S		5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687718	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100689			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Musculoskeletal Stiffness; Pain; Systemic Lupus Erythematosus	Hydroxychloroquine			S				Sanofi
	Arava			S				Sanofi
	Celecoxib			S	Oral	200 Mg, Bid		Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687719	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100913		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Infection; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Hydroxychloroquine Sulfate	S	Oral	300 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate	S		1 Df, Qd		Sanofi
	Leflunomide	S	Oral	20 Mg, Qd		Sanofi
	Methotrexate	S	Subcutaneous	17.5 Mg		Not Reported
	Risedronate Sodium	S				Not Reported
	Risedronate Sodium	S	Oral	35 Mg, Qw		Not Reported
	Actemra	S				Not Reported
	Enbrel	S				Not Reported
	Humira	S	Subcutaneous			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	35 Mg		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 G		Not Reported
	Hydroxychloroquine Sulfate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687721	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100758		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Infection; Malaise; Nasopharyngitis; Product Dose Omission; Rheumatoid Arthritis; Tendon Rupture	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Simponi			S				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687722	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100911		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi
	Arava			S				Sanofi
	Methotrexate			S		25 Mg		Not Reported
	Minocycline Hydrochloride			S				Not Reported

Sulfasalazine	S			Not Reported
Apo-Azathioprine	S		100 Mg	Not Reported
Enbrel	S			Not Reported
Humira	S	Subcutaneous		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Amoxicillin And Clavulanate Potassium	C			Not Reported
Amoxil [Amoxicillin]	C			Not Reported
Bcg	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687786	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101019			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Leflunomide			S		10 Mg, Qd		Sanofi
	Methotrexate			S		15 Mg		Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Rituximab			S		Unk		Not Reported
	Arava			C		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Oral	200 Mg, Bid		Not Reported
	Prednisone			C				Not Reported
	Simponi			C				Not Reported
	Xeljanz			C	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687792	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100987			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Musculoskeletal Stiffness; Polyarthritis; Skin Lesion; Uveitis	Plaquenil			S	Unknown			Sanofi
	Aralen			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687797	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA101046		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Hydroxychloroquine Sulfate			S	Oral	5 Mg		Sanofi
	Methotrexate			S		15 Mg/M2, Qow		Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Oral	1.3 Mg, Bid		Not Reported
	Prednisone			S		Unk		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Triamcinolone Acetonide			S				Sanofi
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Qow		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Qw		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Anakinra			S	Unknown	50 Mg, Qd		Not Reported
	Enbrel			S		1.5 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Immune Globulin (Immunoglobulins Nos)			S	Intravenous (not otherwise specified)			Not Reported

	Infliximab	S	Intravenous (not otherwise specified)	30 Mg, Qw		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Qm		Not Reported
	Triamcinolone Hexacetonide	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687801	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101230			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Arava			S		20 Mg, Qd		Sanofi
	Meloxicam			S	Oral	7.5 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Actemra			S	Subcutaneous	Unk Unk, Qw		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688091	EXPEDITED (15-DAY)		DE, OT	DE-MYLANLABS-2020M1040433		21 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Compartment Syndrome; Acute Respiratory Distress Syndrome; Drug Ineffective; Pancreatitis Necrotising; Sepsis; Shock Haemorrhagic	Prednisolone			S	Intravenous (not otherwise specified)	Pulse Therapy		Not Reported
	Prednisolone			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Mylan
	Plasma			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688196	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584496		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688210	EXPEDITED (15-DAY)		OT	NVSC2020IT104815		52 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Interaction; Hepatic Failure; Pneumonia Viral; Product Use In Unapproved Indication	Tacrolimus			S	Unknown	Unk		Novartis
	Tacrolimus			S				Novartis
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ritonavir			S	Unknown	Unk		Not Reported
	Ritonavir			S				Not Reported
	Mycophenolate Mofetil			C	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			C				Not Reported
	Darunavir			C	Unknown	Unk		Not Reported
	Darunavir			C				Not Reported
	Cobicistat			C	Unknown	Unk		Not Reported
	Cobicistat			C				Not Reported
	Colchicine			C	Unknown	1 Mg On Day 8		Not Reported
	Colchicine			C	Unknown	0.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688319	NON-EXPEDITED			US-CELGENEUS-USA-20200404981			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Diarrhoea; Headache	Otezla			S	Oral	60 Milligram		Celgene
	Synthroid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Cosentyx			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Vitamin D			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Effexor			C	Unknown			Not Reported
	Baby Aspirin			C	Unknown			Not Reported
	Prilosec			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Femara			C	Unknown			Not Reported
	Prozosin			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Doxorubicin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688557	EXPEDITED (15-DAY)		DE, HO, OT	FR-ADVANZ PHARMA-202003002806			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Failure; Off Label Use; Organ Failure; Septic Shock	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd		Concordia
	Rocephine			C		Unk		Not Reported
	Etomidate			C		Unk		Not Reported

Midazolam	C	Unk	Not Reported
Suxamethonium	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688648	EXPEDITED (15-DAY)		DE, OT	ES-TEVA-2020-ES-1225642		21 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hepatitis; Hypocoagulable State; Pancreatitis Acute	Hidroxicloroquina (2143a)			S	Oral	400mg/24h		Teva
	Linezolid (1279a)			S	Intravenous (not otherwise specified)			Teva
	Ambisome 50 Mg Polvo Para Dispersion Para Perfusion , 10 Viales			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688686	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-13364		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported

Sulfasalazine	S	Oral	Unknown		Not Reported
Tocilizumab	S	Unknown	Unknown		Not Reported
Desoximetasone	C	Unknown	Unknown		Not Reported
Methotrexate	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688704	EXPEDITED (15-DAY)		OT	BR-ADVANZ PHARMA-202004002845			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Blindness; Cataract	Hydroxychloroquine			S	Oral	1 Dosage Form, Qd (Coated Tablet)		Concordia
	Depakote			C		Unk		Not Reported
	Ozempic			C		Unk		Not Reported
	Selozok			C		Unk		Not Reported
	Pressetina			C		Unk		Not Reported
	Glifage			C		Unk		Not Reported
	Zetia			C		Unk		Not Reported
	Rosuvastatina			C		Unk		Not Reported
	Marevan			C		Unk		Not Reported
	Topiramato			C		Unk		Not Reported
	Venlafaxine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688866	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100693			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S		Unk		Sanofi

Fluctuation; Therapeutic Product Effect Incomplete	Arava	S				Sanofi
	Bisoprolol Salt Not Specified	S				Not Reported
	Cefaclor	S				Not Reported
	Celecoxib	S	Oral	200 Mg, Qd (1 Df, Every 1 Day)		Not Reported
	Demerol	S				Sanofi
	Erythromycin	S				Sanofi
	Erythromycin	S				Sanofi
	Levofloxacin	S				Not Reported
	Pregabalin	S				Not Reported
	Methotrexate	S				Not Reported
	Metronidazole	S				Sanofi
	Norfloxacin	S				Not Reported
	Prednisone	S				Not Reported
	Sulfasalazine	S				Not Reported
	Arthrotec	S				Not Reported
	Humira	S	Subcutaneous	400 Mg		Not Reported
	Meperidine Hydrochloride	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688868	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100832			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deformity; Movement Disorder; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Plaquenil			S				Sanofi
	Methotrexate			S				Not Reported
	Leflunomide			S		Unk		Sanofi
	Chloroquine Sulfate			S				Sanofi
	Myochrysine			S				Not Reported
	Humira			S				Not Reported
	Remicade			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688869	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100754			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Rheumatoid Arthritis;	Hydroxychloroquine Sulfate			S		200 Mg, Qd		Sanofi
	Arava			S				Sanofi

Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Methotrexate	S	Oral	25 Mg, Qw		Not Reported
	Myochrysine	S	Intramuscular	25 Mg, Qw		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Enbrel	S		50 Mg, Qw		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688871	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100853			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Plaquenil			S	Unknown			Sanofi
	Aralen			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688872	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100674		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Fibromyalgia; Lymphoedema; Obesity; Pneumocystis Jirovecii Pneumonia; Pulmonary Embolism	Hydroxychloroquine			S				Sanofi
	Methotrexate			S				Not Reported
	Leflunomide			S				Sanofi
	Orencia			S				Not Reported
	Xeljanz			S				Not Reported
	Actemra			S	Subcutaneous	162 Mg, Qw		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydrocortisone	C	Unk Unk, Bid	Not Reported
	Pantoloc [Pantoprazole]	C		Not Reported
	Prednisone	C	20 Mg, Qd	Not Reported
	Xarelto	C		Not Reported
	Tylenol 8 Hr Arthritis Pain	C	2 Df, Bid	Not Reported
	Calcium & Vitamin D3	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688879	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200421346		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Product Use Issue; Uveitis	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Adalimumab			S	Subcutaneous			Not Reported
	Leflunomide			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Sarilumab			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S				Not Reported
	Tocilizumab			S				Not Reported
	Tofacitinib			S				Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone			C				Not Reported
	Rabeprazole Sodium			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688898	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-13469			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown; Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown; Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Sulfasalazine			S	Oral	Unknown		Not Reported
	Methotrexate			C	Oral			Not Reported
	Desoximetasone			C	Unknown	Unknown		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688907	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101008		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Impaired Work Ability; Nasopharyngitis; Rheumatoid Arthritis;	Hydroxychloroquine Sulfate			S	Oral	200 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Unk		Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported

Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Celebrex	S	Unknown		Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	25 Mg	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Vioxx	S	Oral		Not Reported
	Xeljanz	S	Oral	5 Mg	Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Wellbutrin	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688909	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100917			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased; Therapeutic Response Decreased	Hydroxychloroquine Sulfate			S		200 Mg, Qd		Sanofi
	Arava			S				Sanofi
	Methotrexate			S	Oral	25 Mg,Qw		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S		50 Mg,Qw		Not Reported
	Myochrysine			S		25 Mg,Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688918	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101017			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S	Oral	20 Mg		Sanofi
	Methotrexate			S				Not Reported
	Enbrel			S				Not Reported
	Actemra			S				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688919	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100879			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deep Vein Thrombosis; Diarrhoea; Rash; Skin Infection; Systemic Lupus Erythematosus; Transaminases Increased; Treatment Failure	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Azathioprine			S				Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Sulfasalazine			S				Not Reported
	Orencia			S	Subcutaneous	125 Mg, Qw		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk, Q6w		Not Reported
	Pariet			C		20 Mg, Qd		Not Reported
	Folic Acid			C		5 Mg, Qd; 1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688920	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100863			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi

Leflunomide	S	Oral	20 Mg, Qd		Sanofi
Methotrexate	S	Unknown	20 Mg, Qw		Not Reported
Methotrexate	S		15 Mg, Qw		Not Reported
Actemra	S	Unknown			Not Reported
Enbrel	S	Unknown	25 Mg, Qow		Not Reported
Humira	S	Subcutaneous	40 Mg, Qow		Not Reported
Orencia	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Q6w		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sulfasalazine	C	Unknown			Not Reported
Wellbutrin	C	Oral			Not Reported
Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689015	DIRECT	Y	DE			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure; Sudden Death	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689055	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226544		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Infection; Loss Of Consciousness; Mobility Decreased; Nausea; Rheumatoid Arthritis	Leflunomide			S	Oral	20 Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Risedronate Sodium			S	Oral			Teva
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported

Apo-Leflunomide	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Gold	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Unknown	300 Milligram Daily;	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral	300 Milligram Daily;	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	C	Unknown		Not Reported
Risedronate	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689154	EXPEDITED (15-DAY)		CA, DS, OT	FR-UCBSA-8027844			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chondrodystrophy; Chondropathy; Dysmorphism; Low Birth Weight Baby; Maternal Exposure During Pregnancy	Keppra			S		3000mg Daily		Not Reported
	Keppra			S	Transplacental	Unk		Not Reported
	Trileptal			S	Transplacental			Not Reported
	Plaquenil			S	Transplacental			Not Reported
	Paracetamol			S	Transplacental			Not Reported
	Cortancyl			C	Transplacental			Not Reported

	Actonel	C	Transplacental	Not Reported
	Orocal D3	C	Transplacental	Not Reported
	Diffu-K	C	Transplacental	Not Reported
	Speciafoldine	C	Transplacental	Not Reported
	Kaleorid	C	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689241	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1225072			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neutropenia; Rash; White Blood Cell Count Decreased	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown	20 Mg, 1 Every 1 Week		Barr
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689616	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1224923			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Rheumatoid Arthritis; Weight Increased	Indometacin			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Morphine Sulfate			S	Unknown			Actavis
	Prednisone			S	Unknown	12.5 Milligram Daily;		Actavis
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

			otherwise specified)		
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689685	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226003		66 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Amoxixilina / Clavulanico (Amoxicillin\Clavulanic Acid)			S	Oral	875 Mg,1 Df		Teva
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689693	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-2016133US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Plaquenil			S	Oral	600 Mg, Qd		Not Reported
	Azithromycine Sandoz [Azithromycin Monohydrate]			S	Oral	250 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689715	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101218			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate			S				Sanofi
	Bisoprolol Fumarate			S				Not Reported
	Cefixime			S				Not Reported
	Methotrexate			S				Not Reported
	Morphine Hydrochloride			S				Not Reported
	Nifedipine			S				Not Reported

Pantoprazole	S				Not Reported
Prednisone	S				Not Reported
Clonazepam	S				Not Reported
Zantac	S				Sanofi
Zopiclone	S				Not Reported
Azathioprine	S	Oral	100 Mg		Not Reported
Infliximab	S	Intravenous (not otherwise specified)	5 Mg/Kg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689717	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101219			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Sanofi
	Leflunomide			S	Unknown	10 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	15 Mg		Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689721	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100822			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi
	Arava			S	Unknown			Sanofi
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Methotrexate			S				Not Reported

Sulfasalazine	S				Not Reported
Azathioprine	S	Unknown	100 Mg		Not Reported
Enbrel	S	Unknown			Not Reported
Humira	S	Subcutaneous			Not Reported
Minocycline	S	Unknown			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Xeljanz	S	Unknown	5 Mg, Bid (2 Every 1 Day)		Not Reported
Hydroxychloroquine Sulfate	C	Unknown			Not Reported
Leflunomide	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689724	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101252			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Bursitis; Chronic Obstructive Pulmonary Disease; Drug Hypersensitivity; Gastrectomy; Hypothyroidism; Mammoplasty; Obesity; Osteoarthritis; Osteopenia; Phlebectomy; Synovitis; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Leflunomide			S		10 Mg, Qd		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Cosentyx			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow, Solution Subcutaneous		Not Reported
	N-(3-Chloroallyl)Hexaminium Chloride			S				Not Reported
	Penicillin G [Benzylpenicillin]			S				Not Reported
	Simponi			S	Subcutaneous	50 Mg, Qm, Solution Subcutaneous		Not Reported
	Stelara			S		Unk, Q8w		Not Reported
	Stelara			S	Subcutaneous	Unk, Solution Subcutaneous		Not Reported
	Cetirizine			C		10 Mg, Bid		Not Reported
	Enbrel			C		50 Mg, Qw		Not Reported
	Lasix [Furosemide]			C		40 Mg, Qm		Not Reported

	Montelukast	C	10 Mg, Qd	Not Reported
	Synthroid	C	75 Mg, Qd	Not Reported
	Terbutaline Sulfate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689729	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101216			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Meloxicam			S	Oral	7.5 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Actemra			S	Subcutaneous	1 Df, Qw		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689730	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101215			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Prednisone			S				Not Reported
	Actemra			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689734	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101213		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Mg, Qd		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Mg		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Acetaminophen			C				Not Reported
	Anakinra			C	Unknown	100 Mg		Not Reported
	Ativan			C				Not Reported
	Codeine			C				Not Reported
	Darifenacine			C				Not Reported
	Desoximetasone			C				Not Reported
	Dilaudid			C				Not Reported
	Diphenhydramine			C				Not Reported
	Furosemide			C				Not Reported
	Hydromorphone			C				Not Reported
	Kadian			C				Not Reported
	Kenalog [Triamcinolone Acetonide]			C	Unknown	40 Mg		Not Reported
	Loperamide			C				Not Reported
	Norflex [Orphenadrine Citrate]			C				Not Reported
	Omnaris			C				Not Reported
	Oxyneo			C				Not Reported
	Pantoprazole			C				Not Reported
	Restasis			C				Not Reported

	Rituximab	C	Intravenous (not otherwise specified)			Not Reported
	Synthroid	C				Not Reported
	Trimethoprim	C				Not Reported
	Urispas	C	Unknown	200 Mg		Not Reported
	Vagifem	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689790	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1225158		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Joint Range Of Motion Decreased; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	20 Mg, 1 Every 1 Week		Barr
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depo-Medrol			C		80 Milligram Daily; Suspension Intraarticular		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689979	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2609900-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			C				Not Reported
	Celebrex			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17690106	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA102627		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Voltaren			S	Unknown	Unk		Novartis
	Diclofenac			S	Unknown	Unk		Novartis
	Diclofenac Potassium			S	Unknown	Unk		Novartis
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

	Rituximab		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17690600	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-019705		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Loss Of Consciousness; Malaise; Ventricular Extrasystoles	Azithromycin			S	Oral	Unk		Aurobindo
	Plaquenil			S	Oral	Unk		Not Reported
	Lovenox			C	Oral	Unk		Not Reported
	Paracetamol			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17690705	EXPEDITED (15-DAY)		HO	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-244413		35 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Rash	Ciprofloxacin			S	Unknown	800 Milligram, Daily		Ranbaxy
	Doxycycline			S	Oral	Unk		Sun
	Hydroxychloroquine			S	Oral	600 Milligram, Daily		Sun
	Moxifloxacin			S	Oral	400 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17690772	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226789		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Risedronate			S	Oral			Teva
	Risedronate			S	Unknown			Teva

Intolerance; Hypertension; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Actemra	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	300 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	11607841	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-JNJFOC-20150923280		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adjustment Disorder With Depressed Mood; Adverse Event; Alopecia; Amnesia; Anti-Cyclic Citrullinated Peptide Antibody Positive;	Simponi			S	Subcutaneous			Janssen
	Stelara			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Zyrtec			S	Oral			Johnson And Johnson

Arthropathy; Blister; Breast Cancer Stage Iii; Condition Aggravated; Contraindicated Product Administered; Delirium; Depression; Diarrhoea; Disability; Discomfort; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; Gait Disturbance; General Physical Health Deterioration; Glossodynia; Glossodynia; Grip Strength Decreased; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infection; Infusion Related Reaction; Joint Range Of Motion Decreased; Joint Swelling; Knee Arthroplasty; Memory Impairment; Mobility Decreased; Muscular Weakness; Off Label Use; Pain; Pain In Extremity; Pemphigus; Pericarditis; Peripheral Swelling; Product Use In Unapproved Indication; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Seronegative	Zyrtec	S	Unknown		Johnson And Johnson
	Reactine (Cetirizine Dihydrochloride)	S	Oral		Johnson And Johnson
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Sunconjunctival		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Therpay Duration 11 Monts	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Fosamax	S	Oral		Not Reported
	Plaquenil	S	Oral		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution For Injection/Infusion	Not Reported
	Rituxan	S	Intravesical	Solution For Injection/Infusion	Not Reported

Arthritis; Sleep Disorder; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Treatment Noncompliance; Type 2 Diabetes Mellitus; Walking Aid User; Weight Decreased; Wound; Wound Infection	Phthalylsulfathiazole	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Subcutaneous	Not Reported
	Cortisone	S	Topical	Not Reported
	Cortisone	S	Oral	Not Reported
	Cortisone Acetate	S	Oral	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Cortisone Acetate	S	Oral	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Desoximetasone	S	Cutaneous	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Urethral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Topicort (Hydrocortisone Acetate)	S	Subcutaneous	Not Reported
	Topicort (Hydrocortisone Acetate)	S	Cutaneous	Not Reported
	Topicort (Hydrocortisone	S	Oral	Not Reported

Acetate)			
Topicort (Hydrocortisone Acetate)	S	Subcutaneous	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Acetaminophen	S	Oral	Not Reported
Apo Hydroxyquine	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Paracetamol	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Diclofenac	S	Unknown	Not Reported
Cosentyx	S		Not Reported
Salazopyrin	C	Unknown	Not Reported
Tofacitinib Citrate	C	Unknown	Not Reported
Atasol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	12912114	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20160308952			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Conjunctivitis; Fatigue; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Viral Infection	Simponi			S	Subcutaneous			Janssen
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Hydroxychloroquine /00072603/	S	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Amlodipine Besilate	C		Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Oral	Not Reported
	Lyrica	C	Oral	Not Reported
	Mavik	C	Unknown	Not Reported
	Olopatadine Hydrochloride	C	Ophthalmic	Not Reported
	Prednisone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	12914315	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-093127		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Enthesopathy; Erythema; Gastric	Orencia			S	Intravenous (not otherwise specified)	760 Milligram, Qwk		Bristol Myers Squibb
	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Tocilizumab			S	Unknown	360 Milligram, Q4wk		Not Reported
	Tocilizumab			S	Unknown	680 Milligram, Q4wk		Not Reported
	Tocilizumab			S	Unknown	360 Milligram, Qwk		Not Reported
	Tocilizumab			S	Unknown	360 Milligram		Not Reported
	Tocilizumab			S	Unknown	680 Milligram		Not Reported
	Tocilizumab			S	Unknown	380 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram, Qd		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram, Bid		Not Reported
	Rituximab			S	Unknown	1000 Milligram, Bid		Not Reported

Disorder; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Disorder; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Tongue Disorder; Ulcer	Methotrexate	S	Subcutaneous	10 Milligram, Q2wk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Q4wk	Not Reported
	Methotrexate	S	Unknown	12 Milligram, Q4wk	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Q4wk	Not Reported
	Methotrexate	S	Unknown	17.5 Milligram, Q4wk	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, Q2wk	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Q2wk	Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Q4wk	Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	380 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	500 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Milligram, Q2wk	Not Reported
	Enbrel	S	Unknown	25 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	50 Milligram, Qwk	Not Reported

Enbrel	S	Subcutaneous	Unk	Not Reported
Codeine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Oral	20 Milligram	Not Reported
Hydroxychloroquine	S	Oral	200 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	360 Milligram, Qmo	Not Reported
Hydroxychloroquine	S	Unknown	680 Milligram	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Qmo	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Q2wk	Not Reported
Myochrysine	S	Intramuscular	25 Milligram, Qwk	Not Reported
Myochrysine	S	Unknown	10 Milligram	Not Reported
Myochrysine	S	Unknown	50 Milligram, Qmo	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Alendronate Sodium	S	Unknown	70 Milligram, Q4wk	Not Reported
Alendronate Sodium	S	Unknown	70 Milligram, Qwk	Not Reported
Sulfasalazine	S	Endocervical	500 Milligram	Not Reported
Sulfasalazine	S	Endocervical	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Rituxan	S	Unknown	1000 Milligram, Bid	Not Reported
Alendronic Acid	S	Unknown	70 Milligram, Qwk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Cyclosporin	C	Unknown	Unk	Not Reported
Cyclosporin	C	Unknown	150 Milligram, Qd	Not Reported
Actemra	S	Unknown	680 Milligram, Q4wk	Not Reported
Actemra	S	Unknown	360 Milligram, Q4wk	Not Reported
Actemra	S	Unknown	2.68 Milligram, Q4wk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Otezla	S	Unknown	Unk	Not Reported

Simponi	S	Subcutaneous	680 Milligram, Qmo	Not Reported
Simponi	S	Unknown	360 Milligram, Qmo	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Apo-Ibuprofen	S	Oral	Unk	Not Reported
Apremilast	S	Unknown	60 Milligram, Bid	Not Reported
Apremilast	S	Unknown		Not Reported
Apremilast	S	Unknown		Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Ibuprofen	S	Oral	600 Milligram, Qd	Not Reported
Infliximab	S	Oral	Unk	Not Reported
Motrin [Ibuprofen]	S	Oral	600 Milligram, Qd	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk	Not Reported
Colchicine	C	Unknown	Unk	Not Reported
Dexilant	C	Oral	Unk	Not Reported
Febuxostat	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Mogadon	C	Oral	5 Milligram	Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported
Uloric	C	Oral	80 Milligram, Bid	Not Reported
Prednisolone	C	Unknown	10 Milligram	Not Reported
Prednisolone	C	Unknown	20 Milligram	Not Reported
Prednisone	C	Unknown	20 Milligram	Not Reported
Prednisone	C	Unknown	10 Milligram, Qd	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Alendronate	C	Unknown	70 Milligram, Qwk	Not Reported

Azathioprine	S	Unknown	Unk		Not Reported
Celebrex	S	Unknown	Unk		Not Reported
Etanercept	S	Unknown	25 Milligram, Q2wk		Not Reported
Methotrexate	S	Oral	10 Milligram, Qwk		Not Reported
Naproxen	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	13068783	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20161203380			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Intolerance; Headache; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Tremor	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Enbrel			S	Subcutaneous	Duration Is 9 Months		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Cyclical For -244.0		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Morphine /00036302/			S	Topical	1.0 Dosage Form		Not Reported
	Naprosyn /00256201/			S				Not Reported
	Zopiclone			C	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Pantoprazole Magnesium			C	Oral			Not Reported
	Tenofovir Disoproxil Fumarate			C	Oral			Not Reported

	Xeljanz	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Tenofovir Disoproxil	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	13319448	EXPEDITED (15-DAY)		OT	CA-ROCHE-1902949			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)	Powder For Suspension		Not Reported
	Desoximetasone			C	Oral			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Cortisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	14908110	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP013244			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug	Meloxicam			S	Oral	7.5 Mg, Qd		Apotex

Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine	S	Unknown	Unk		Apotex
	Methotrexate	S	Oral	20 Mg, Q.Wk.		Not Reported
	Mobicox	S	Oral	7.5 Mg, Qd		Not Reported
	Actemra	S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Arava	S	Unknown	20 Mg, Qd		Not Reported
	Arava	S	Unknown	20 Mg, Q.Wk.		Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium	S	Oral	20 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/	S	Unknown			Not Reported
	Sulfasalazine	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	14999486	EXPEDITED (15-DAY)		DE, OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-175486		67 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Death; Drug Interaction; Haemoptysis; International Normalised Ratio Decreased; Labelled Drug-Drug Interaction Medication Error; Platelet Count Decreased; Product Administration Error; Pyrexia	Lorazepam			S	Unknown	Unk ()		Sun
	Montelukast			S	Unknown	Unk ()		Not Reported
	Celecoxib			S	Unknown	Unk ()		Not Reported
	Warfarin			S	Unknown	Regimen 1 ()		Not Reported
	Influenza Vaccine Inactivated			S	Unknown	Unk ()		Not Reported
	Asa			S	Endocervical	Unk ()		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk ()		Not Reported
	Hydroxychloroquine			S	Unknown	Unk ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	15268901	EXPEDITED (15-DAY)		OT	CA-ROCHE-2168136			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculosis	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Minocycline	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Clavulanate Potassium	C		Not Reported
	Amoxil [Amoxicillin]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	15360741	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-TORRENT-00009759			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Acetylsalicylic Acid			S	Transplacental	From Gestational Week 0-14		Unknown
	Aliskiren			S	Transplacental	300 [Mg/D]; 0-4.6 Gestational Week		Unknown
	Clexane			S	Transplacental	Exposure Duration: 0-14 Weeks		Unknown
	Dalteparin Sodium			S	Transplacental	Unknown		Unknown
	Enoxaparin Sodium			S	Transplacental	From Gestational Week 0-14		Unknown
	Ezetimibe			S	Transplacental	From Gestational Week 0-14		Unknown
	Heparin			S	Transplacental	Unknown		Not Reported
	Hydroxychloroquine			S	Transplacental	From Gestational Week 0-14		Unknown

Metamizole	S	Transplacental	From Gestational Week 0-14	Not Reported
Nicotine	S	Transplacental	From Gestational Week 0-14	Unknown
Pantoprazole	S	Transplacental	40 [Mg/D]; 0-13.6 Gestational Week	Not Reported
Prednisolone	S	Transplacental	From Gestational Week 0-14	Unknown
Ramipril	S	Transplacental	20 Mg Per Day, Exposure Duration: 0-113+6 Weeks / Maternal Dose 20 Mg, Unknown	Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Unknown
Salbutamol	S	Transplacental	From Gestational Week 0-14	Unknown
Simvastatin	S	Transplacental	From Gestational Week 0-14	Not Reported
Tacrolimus	S	Transplacental	From Gestational Week 0-14	Unknown
Torsemide	S	Transplacental	From Gestational Week 0-14	Not Reported
Xarelto	S	Transplacental	From Gestational Week 0-5	Unknown
Cytotec	C	Transplacental	Unk; 13.6 Gestational Week	Unknown
Mifegyne	C	Transplacental	Unk; 13.6 Gestational Week	Unknown
Novaminsulfon	S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	15623907	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2554647-00		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Off Label Use; Synovitis; Therapeutic Response Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Vorhyaluronidase Alfa			S	Intravenous (not otherwise specified)			Not Reported
	Amitriptyline Hydrochloride			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Elavil			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Premarin			C	Unknown			Not Reported
	Tenormin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Sumatriptan Succinate			C	Unknown			Not Reported
	Imitrex			C	Unknown			Not Reported

	Sumatriptan	C	Unknown		Not Reported
	Amitriptyline	C			Not Reported
	Tofacitinib	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	15624422	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556711-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Deformity; Diarrhoea; Disease Progression; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Warfarin			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Warfarin			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	15629635	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557205-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; Contraindicated Product Administered; Drug	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported

Ineffective; Finger Deformity; Gait Disturbance; General Physical Health Deterioration; Knee Arthroplasty; Rheumatoid Arthritis; Spinal Disorder; Therapeutic Product Effect Decreased	Arava		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Enbrel		S		Not Reported
	Methotrexate		S	Unknown	Not Reported
	Methotrexate		S		Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Orencia		S		Not Reported
	Plaquenil		S	Unknown	Not Reported
	Plaquenil		S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	15668157	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570296-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Demerol			S	Unknown			Not Reported
	Erythro Base			S	Unknown			Not Reported
	Erythromycin Estolate			S	Unknown			Not Reported
	Levofloxacin Hemihydrate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Meperidine Hydrochloride			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Metronidazole			S	Intravenous (not	Dosage Form-Liquid		Not Reported

			otherwise specified)	Intravenous	
	Norfloxacin	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Erythromycin	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Levofloxacin	S	Unknown		Not Reported
	Bisoprolol Fumarate	S	Unknown		Not Reported
	Celecoxib	S	Oral		Not Reported
	Meperidine	S	Unknown		Not Reported
	Pregabalin	S	Unknown		Not Reported
	Cefaclor	S	Unknown		Not Reported
	Leflunomide Sandoz	S	Unknown		Not Reported
	Noritate	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Act Diclo Miso	S	Unknown	Enteric Coated	Not Reported
	Diclofenac + Misoprostol Aurovitas	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	15676976	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573583-00		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Enbrel	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Risedronate Sodium	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Plaquenil	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Actonel	S	Unknown		Not Reported
Apo Risedronate	S	Unknown		Not Reported
Apo Risedronate	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Risedronate	S	Unknown		Not Reported
Apo Risedronate	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Hydroxychloroquine	C			Not Reported
Hydroxychloroquine Sulfate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	16080823	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013796		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Celecoxib Capsules			S	Oral	Unk		Aurobindo
	Celecoxib			S	Unknown	Unk		Aurobindo
	Celecoxib			S				Aurobindo

Actemra	S	Unknown	Unk	Not Reported
Anakinra	S	Unknown	100 Milligram	Not Reported
Prednisone	S	Unknown	7 Milligram, Once A Day	Not Reported
Apo-Prednisone	S	Unknown	7 Milligram, Once A Day	Not Reported
Celebrex	S	Oral	Unk	Not Reported
Celebrex	S			Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	1 Milliliter, Every Week	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Celebrex	S	Unknown	Unk	Not Reported
Cimzia	S	Unknown	Unk	Not Reported
Humira	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	16639635	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2867070-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fibrosis; Ill-Defined Disorder; Inflammation; Joint Swelling; Musculoskeletal	Humira			S	Subcutaneous			Not Reported
	Sulfasalazin			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

Stiffness; Treatment Failure	Prednisone	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Etanercept	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17531498	EXPEDITED (15-DAY)		DS, HO, OT	CA-GLAXOSMITHKLINE-CA2020044221		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Grip Strength Decreased; Joint Swelling; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Diclofenac			S	Oral	1 Df		Glaxosmithkline
	Diclofenac			S	Oral	2 Df, Qd		Glaxosmithkline
	Diclofenac			S	Oral	75 Mg, Bid		Glaxosmithkline
	Diclofenac			S	Oral	Unk		Glaxosmithkline
	Diclofenac			S	Oral	Unk, Qd		Glaxosmithkline
	Diclofenac			S	Oral	Unk		Glaxosmithkline
	Diclofenac Potassium			S	Oral	Unk		Glaxosmithkline
	Pantoprazole			S	Unknown	Unk		Glaxosmithkline
	Pantoprazole			S	Unknown	Unk		Glaxosmithkline
	Pantoprazole			S	Unknown	Unk		Glaxosmithkline
	Pantoprazole			S	Unknown	Unk		Glaxosmithkline
	Voltaren Sr			S	Oral	2 Df, Qd (75 Mg)		Glaxosmithkline
	Voltaren Sr			S	Oral	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	Unk		Glaxosmithkline
	Cambia			S	Oral	Unk, Qd		Glaxosmithkline
	Cambia			S	Oral	Unk		Glaxosmithkline
	Cambia			S	Unknown	75 Mg, Bid		Glaxosmithkline
	Lisinopril			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	1 Df, Qw		Not Reported
	Sulfasalazine			S	Oral	2 Df, Qd (1 Gram)		Not Reported

Sulfasalazine	S	Unknown	1 Df, Qd (500 Mg)		Not Reported
Plaquenil	S	Oral	1 Df, Qd		Not Reported
Synthroid	S	Unknown	Unk		Not Reported
Xeljanz	S	Oral	2 Df, Qd		Not Reported
Gold	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17685737	EXPEDITED (15-DAY)		DE	IE-JNJFOC-20200410813		57 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Ineffective	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Mabthera			S				Not Reported
	Humira			S				Not Reported
	Protium			C	Unknown			Not Reported
	Agomelatine			C	Unknown			Not Reported
	Alendronate (Generic)			C	Unknown			Not Reported
	Levothyroxine Sodium (G)			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Prednisolone (Generic)			C	Unknown			Not Reported
	Depo-Medrone			C	Unknown			Not Reported
	Sodium Aurothiomalate (G)			C	Unknown			Not Reported
	Methotrexate (G)			C	Unknown			Not Reported
	Sulfasalazine (G)			C	Unknown			Not Reported
	Seroquel			C				Not Reported
	Agomelatine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17690789	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584439			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Inflammatory Marker Increased; Joint Swelling; Musculoskeletal Stiffness; Presyncope	Rituximab			S	Intravenous drip			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17690794	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226002		73 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily; 500 Mg/24h		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	200 Milligram Daily; 200 Mg/24h		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Milligram Daily; 600mg/24h		Not Reported
	Tocilizumab (8289a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily; 2gr/24h		Not Reported
	Ceftriaxona (501a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17690857	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-032312		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Dermatitis; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Neoplasm Skin; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Incomplete; Ulcer	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Alendronate Sodium			S	Unknown	70 Milligram, Qwk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	Unk Unk, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	680 Milligram		Not Reported
	Ciclosporin			C	Unknown	150 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Rituxan			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17690973	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES			Unknown	GBR

LIMITED-IPC-2020-GB-001159

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Drug Intolerance; Gastrointestinal Disorder; Headache; Nausea; Urinary Tract Infection	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	20 Milligram, Qd		Not Reported
	Prednisolone			S	Unknown	9 Milligram, Qd		Not Reported
	Amoxicillin			S	Unknown	Unk		Not Reported
	Amoxicillin			S				Not Reported
	Co-Amoxiclav			S	Unknown	Unk		Not Reported
	Gentamycin			S	Unknown	Unk		Not Reported
	Tobramycin			S	Unknown	Unk		Not Reported
	Colomycin [Colistimethate Sodium]			S	Unknown	Unk		Not Reported
	Doxycycline			S	Unknown	Unk		Not Reported
	Cefaclor			S	Unknown	Unk		Not Reported
	Meropenem			S	Unknown	Unk		Not Reported
	Tazobactam/Piperallin			S	Unknown	Unk		Not Reported
	Ceftazidime			S	Unknown	Unk		Not Reported
	Cefradine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17690976	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584770			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17691161	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101231			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Infection; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Arava			S		20 Mg		Sanofi
	Arava			S		Unk		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Leflunomide			S		Unk		Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Methotrexate			S	Subcutaneous	7.5 Mg		Not Reported
	Methotrexate			S	Subcutaneous	7.5 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20.0 Mg		Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Diclofenac Sodium And			S		50 Mg, Bid		Not Reported

	Misoprostol				
	Arthrotec	C	50 Mg, Bid		Not Reported
	Gold	C			Not Reported
	Imuran [Azathioprine]	C			Not Reported
	Vitamin D3	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17691162	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA100870		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Discomfort; Rash; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Sanofi
	Leflunomide			S	Oral	10 Mg		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Cefazolin			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Viread			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17691425	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1225669		33 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Mg / 12h The First Day, Then 400 Mg / 24h, Unit Dose 400mg		Teva

	Hidroxicloroquina (2143a)	S	Oral	400 Mg / 12h The First Day, Then 400 Mg / 24h, Unit Dose 400 Mg	Teva
	Azitromicina (7019a)	S	Oral	500mg / 24h 1st Dose, Then 250mg / 24h, Unit Does 500 Mg	Not Reported
	Azitromicina (7019a)	S	Oral	500mg / 24h 1st Dose, Then 250mg / 24h, Unit Dose 250 Mg	Not Reported
	Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	2gr/24h, Unit Dose 2 Gm	Not Reported
	Ceftriaxona (501a)	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17691428	EXPEDITED (15-DAY)		HO, OT	ES-SA-2020SA104277		80 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute; Off Label Use; Thrombocytopenia	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, Qd		Not Reported
	Ceftriaxone			S				Not Reported
	Enoxaparin Sodium			S	Subcutaneous	40 Mg, Qd		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17691526	EXPEDITED (15-DAY)		HO, LT	SI-ABBVIE-20K-261-3372991-00		48 YR	Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Thrombocytopenia; Thrombocytopenia	Kaletra			S	Oral	(80mg+20mg)/Ml Oral Solution, Dose 400mg/100 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Piperacillin/Tazobactam			C				Not Reported

	Esmeron	C	Not Reported
	Metoclopramid	C	Not Reported
	Analgin	C	Not Reported
	Pantoprazole	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17691529	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202003003107			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thyroid Cancer	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17691630	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101016			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Celecoxib			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Bifidobacterium Bifidum			C	Unknown			Not Reported
	Loperamide			C	Oral			Not Reported
	Pantoprazole			C	Unknown	Unk Unk, Tid		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17691787	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584596			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Neck Pain; Off Label Use; Rheumatoid Factor Positive; Spinal Column Injury; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17691915	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584504			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported

	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17692044	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101011		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition Aggravated; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Arava			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Prednisone			S	Oral	20 Mg		Not Reported
	Myocrisin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown	50 Mg, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Bid		Not Reported
	Rituxan			S	Unknown	1 G, Bid		Not Reported
	Simponi			S	Unknown	50 Mg		Not Reported
	Apo Prednison			S	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17692427	EXPEDITED (15-DAY)		OT	CN-ADVANZ PHARMA-202004003310			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Coronavirus Infection; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17692563	EXPEDITED (15-DAY)		DE, OT	FR-ADVANZ PHARMA-202004003424			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Organ Dysfunction Syndrome; Off Label Use; Overdose; Pneumonia Bacterial; Septic Shock	Hydroxychloroquine			S		600 Mg, Qd Film-Coated Tablet		Concordia
	Hydroxychloroquine			S		400 Mg, Qd Film-Coated Tablet		Concordia
	Hydroxychloroquine			S		200 Mg, Qd Film-Coated Tablet		Concordia
	Hydroxychloroquine			S		400 Mg, Qd Film-Coated Tablet		Concordia
	Cefepim Amomed			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Sufentanil			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Atracurium Besilate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17692890	NON-EXPEDITED			US-AMGEN-USASP2020063491		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Accidental Exposure To Product; Eye Disorder; Injection Site Pain; Pain; Sinusitis	Enbrel		S	Unknown	Unk	Amgen
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17692900	EXPEDITED (15-DAY)		DE	ES-FRESENIUS KABI-FK202003924		95 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Levofloxacin (Manufacturer Unknown)			S	Intravenous (not otherwise specified)			Fresenius Medical Care
	Quetiapine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Risperidone			S	Oral			Not Reported
	Ritonavir/Lopinavir			S	Oral			Not Reported
	Losartan			C	Oral			Not Reported
	Clindamycin Hydrochloride			C	Intravenous (not otherwise specified)			Not Reported
	Lorazepam			C	Oral			Not Reported
	Furosemide			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17692945	EXPEDITED (15-DAY)		OT	CN-ADVANZ PHARMA-202004003226			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Liver Injury; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17693787	EXPEDITED (15-DAY)		DE, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-032939		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sepsis; Synovitis; Terminal State; Thrombosis	Orencia	S	Unknown		Bristol Myers Squibb
	Actemra	S	Unknown		Not Reported
	Doxycycline Hyclate	S	Unknown	50 Milligram	Not Reported
	Enbrel	S	Unknown	Unk, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Unknown	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
	Leflunomide	S	Unknown	10 Milligram, Qd	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Rituximab;Urelumab	C	Unknown		Not Reported
	Simponi	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17693828	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-13401			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Product Use Issue; Rheumatoid Arthritis	Infliximab		S	Intravenous (not otherwise specified)		Not Reported
	Actemra		S	Unknown	Unknown	Not Reported
	Actemra		S	Unknown		Not Reported
	Arava		S	Unknown	Unknown	Not Reported
	Azathioprine		S	Unknown	Unknown	Not Reported
	Ciclosporin		S	Unknown	Unknown	Not Reported
	Cimzia		S	Subcutaneous	Single-Use Pre Filled Syringe, Solution Subcutaneous	Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unknown	Not Reported
	Methotrexate		S	Unknown	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17693966	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200419466		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Cough; Drug Ineffective; Headache; Rheumatoid Arthritis; Treatment Failure; Viral Infection	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Xeljanz	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17694029	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1225643		68 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400mg		Teva
	Hidroxicloroquina (2143a)			S	Oral	1er Día 400 Mg/12 H, A Partir Del 2º Día 400mg/24 H		Teva
	Azitromicina (7019a)			S	Oral	500 Mg 1st Dose, Later 250mg / 24h		Not Reported
	Azitromicina (7019a)			S	Oral			Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Milligram Daily; Single Dose		Not Reported
	Tocilizumab (8289a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17694856	EXPEDITED (15-DAY)		LT	FR-ELI_LILLY_AND_COMPANY-FR202004008033		56 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Olanzapine			S	Oral	7.5 Mg, Daily		Eli Lilly And Co
	Plaquenil Sulfate			S	Oral	800 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17695215	EXPEDITED (15-DAY)		DE	IT-AUROBINDO-AUR-APL-2020-019985		70 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Azithromycin Film-Coated Tablets			S	Oral	500 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17695429	EXPEDITED (15-DAY)		HO	DE-BAXTER-2020BAX008027		31 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epidermal Necrosis; Epidermal Necrosis; Lip Disorder; Lip Disorder; Pigmentation Disorder; Skin Lesion; Skin Lesion; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis; Toxic Epidermal Necrolysis; Toxic Epidermal Necrolysis	Endoxan Lyophilisat			S	Unknown			Baxter
	Leflunomide			S	Unknown			Not Reported
	Trimethoprim/Sulfamethoxazole			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisolone			S	Nasal			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	12764963	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076342		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	1 Dosage Form		Not Reported
	Naproxen			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	5 Milligram, Bid		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			S	Unknown	12.5 Milligram		Not Reported

Xeljanz	S	Oral	50 Milligram, 2 Every 1 Day	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
Aleve	S	Unknown		Not Reported
Methotrexate	S	Unknown	20 Milligram	Not Reported
Cosentyx	S	Unknown	Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Prednisone Teva	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Apo-Naproxen	S	Unknown	Unk	Not Reported
Naproxen Sodium	S	Oral	Unk	Not Reported
Prednisone Acetate	S	Unknown	Unk	Not Reported
Naproxen	C	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	400 Milligram	Not Reported
Folic Acid	C	Subcutaneous	Unk	Not Reported
Methotrexate	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Acetaminophen And Codeine	C	Unknown	Unk	Not Reported
Insulin	C	Unknown	Unk	Not Reported
Metformin	C	Unknown	2 Dosage Form, Bid	Not Reported
Celebrex	C	Unknown	2 Dosage Form, Qd	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	13665971	EXPEDITED (15-DAY)		OT	TN-BAUSCH-BL-2017-019520		33 YR	Female	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Generalised Exanthematous Pustulosis	Prednisolone	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Chloroquine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	13974821	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018007			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Topical	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	14235430	EXPEDITED (15-DAY)		DS, HO, OT	CA-APOTEX-2017AP021569		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis;	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Hydroxyquine			S	Oral	Unk		Apotex
	Apo-Alendronate			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Oral	500 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Alendronate			S	Unknown	70 Mg, Q.I.W		Apotex
	Alendronate			S	Unknown	70 Mg, Q.Wk.		Apotex
	Apo-Ibuprofen			S	Oral	Unk		Apotex
	Ibuprofen			S	Oral	600 Mg, Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Codeine			S	Unknown	Unk		Not Reported
	Apremilast			S	Unknown	60 Mg, Bid		Not Reported
	Apremilast			S				Not Reported
	Apremilast			S				Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Infliximab			S	Oral	Unk		Not Reported
	Motrin			S	Oral	600 Mg, Qd		Not Reported
	Motrin			S	Oral	Unk Unk, Qd		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, Two Every One Week		Not Reported

Therapeutic Response Decreased; Tongue Disorder; Ulcer	Enbrel	S	Unknown	25 Mg, Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	50 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Methotrexate	S	Oral	10 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	12 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	70 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	12 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	12.5 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	17.5 Mg, Q.I.W	Not Reported
	Methotrexate	S	Unknown	12 Mg, Q.I.W	Not Reported
	Methotrexate	S	Unknown	10 Mg, Q.I.W	Not Reported
	Methotrexate	S	Unknown	12.5 Mg, Q.I.W	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Q.O.Wk.	Not Reported
	Methotrexate	S	Unknown	70 Mg, Q.Wk.	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	780 Mg, Q.Wk.	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	I1000 Mg, Q.12h	Not Reported
	Sulfasalazine	S	Endocervical	Unk	Not Reported

Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Actemra	S	Unknown	2.68 Mg, 1 Every 4 Weeks	Not Reported
Actemra	S	Unknown	360 Mg, Q.M.T.	Not Reported
Myochrysine	S	Parenteral	50 Mg, Q.M.T.	Not Reported
Tocilizumab	S	Unknown	360 Mg, One Every Month	Not Reported
Tocilizumab	S	Unknown	680 Mg, One Every Four Week	Not Reported
Tocilizumab	S	Unknown	360 Mg, Unk	Not Reported
Tocilizumab	S	Unknown	380 Mg, Unk	Not Reported
Ciclosporin	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	20 Mg, Unk	Not Reported
Xeljanz	C	Unknown		Not Reported
Humira	C	Unknown	40 Mg, Unk	Not Reported
Methotrexate	C	Subcutaneous	15 Mg, Q.Wk.	Not Reported
Methotrexate	C	Subcutaneous	10 Mg, Unk	Not Reported
Methotrexate	C	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
Methotrexate	C	Unknown	10 Mg, Q.Wk.	Not Reported
Methotrexate	C	Unknown	12.5 Mg, Q.Wk.	Not Reported
Methotrexate	C	Unknown	12 Mg, Q.Wk.	Not Reported
Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported
Tocilizumab	C	Unknown	680 Mg, Unk	Not Reported
Tocilizumab	C	Unknown	360 Mg, Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Mogadon	C	Oral	5 Mg, Unk	Not Reported
Nitrazepam	C	Unknown	5 Mg, Unk	Not Reported
Alendronate	C	Unknown	70 Mg, Q.Wk.	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported
Uloric	C	Unknown	80 Mg, Unk	Not Reported

	Benadryl /00000402/	C	Unknown	Unk	Not Reported
	Colchicine	C	Oral	Unk	Not Reported
	Dexilant	C	Unknown	Unk	Not Reported
	Febuxostat	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	14497211	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-027214			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Arthralgia; Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Extremity Contracture; Joint Swelling; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Synovitis; Vomiting	Abatacept			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Tofacitinib Citrate			S	Oral	5 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Unknown	Unk		Not Reported

	Cymbalta	C	Unknown	Unk	Not Reported
	Hydromorphone	C	Unknown	Unk	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	14921412	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044420		63 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Orencia			S	Subcutaneous	125 Milligram		Bristol Myers Squibb
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	2.0 Dosage Form, Qd		Not Reported
	Hydroxychloroquine			S	Oral	10.0 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Oral	5.0 Milligram, Bid		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Endocervical	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Cyclosporine			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Milligram		Not Reported

Methotrexate	S	Subcutaneous	20 Milligram	Not Reported
Methotrexate	S	Oral	20 Milligram	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Oral		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Ciclosporin	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Oral	2 Dosage Form, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Oral	10 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Apo-Hydroxyquine	S	Oral	Unk	Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
Methotrexate Sodium	S	Oral	20 Milligram	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Xeljanz	C	Unknown	2 Ot, Qd	Not Reported
Xeljanz	C	Oral	10 Milligram, Qd	Not Reported
Xeljanz	C	Oral	5 Milligram, Qd	Not Reported
Xeljanz Xr	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	16731204	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2019152774		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Abdominal Pain Upper; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Diclofenac Sodium	S	Unknown	Unk	Glaxosmithkline
	Voltaren(Diclofenac)	S	Unknown	Unk	Glaxosmithkline
	Voltaren(Diclofenac)	S			Glaxosmithkline
	Voltaren(Diclofenac)	S			Glaxosmithkline
	Voltaren(Diclofenac)	S			Glaxosmithkline
	Vitamin C	S	Unknown	Unk	Glaxosmithkline
	Motrin	S	Unknown	Unk	Glaxosmithkline
	Motrin	S			Glaxosmithkline
	Motrin	S			Glaxosmithkline
	Motrin	S			Glaxosmithkline
	Aspirin	S	Unknown	Unk	Glaxosmithkline
	Aspirin	S			Glaxosmithkline
	Aspirin	S			Glaxosmithkline
	Aspirin	S			Glaxosmithkline
	Diclofenac Potassium	S	Unknown	Unk	Glaxosmithkline
	Clopidogrel	S	Unknown	Unk	Glaxosmithkline
	Clopidogrel	S			Glaxosmithkline
	Clopidogrel	S			Glaxosmithkline
	Clopidogrel	S			Glaxosmithkline
	Ibuprofen	S	Unknown	Unk	Glaxosmithkline
	Sulfamethoxazole	S	Unknown	Unk	Glaxosmithkline
	Arava	S	Oral	Unk	Not Reported
	Arava	S			Not Reported
	Arava	S			Not Reported
	Arava	S			Not Reported
	Asa	S	Unknown	325 Mg (Delayed Release)	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S			Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Humira	S			Not Reported
	Humira	S			Not Reported
	Plaquenil	S	Oral	Unk	Not Reported

	Plaquenil	S			Not Reported
	Plaquenil	S			Not Reported
	Plaquenil	S			Not Reported
	Apo-Diclofenac	S	Topical	Unk	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Naproxen	S			Not Reported
	Naproxen	S			Not Reported
	Naproxen	S			Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	Unk	Not Reported
	Tramadol	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Trimethoprim	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Gold	S			Not Reported
	Gold	S			Not Reported
	Gold	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	16748699	EXPEDITED (15-DAY)		OT	CA-ROCHE-2381845		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17004240	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-103496		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Aleve			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Simponi			C	Subcutaneous	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17035098	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136345		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition Aggravated; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Prednisone			S	Oral	20 Milligram Daily;		Actavis
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Rituximab			S	Unknown	2000 Milligram Daily;		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	2000 Milligram Daily;		Not Reported
	Rituxan			S	Unknown	2 Gram Daily;		Not Reported
	Tofacitinib Citrate			S	Unknown	10 Milligram Daily;		Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17191010	EXPEDITED (15-DAY)		OT	NVSC2019CA076411			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Etanercept			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg Solution		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Tocilizumab			S	Subcutaneous	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cortisone Acetate			S	Topical	25 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported

Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Plaquenil	S	Unknown	Unk		Not Reported
Prednisone	S	Oral	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sulfasalazine	S	Subcutaneous	500 Mg		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17350586	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-004765			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown	8 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Sodium Aurothiomalate			S	Parenteral	50 Milligram		Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17554482	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present; Gastroenteritis Viral; Human Anti-Human Antibody Test; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	250 Milligram		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	200 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Qwk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Q2wk		Not Reported
	Adalimumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Anakinra			S	Unknown	50 Milligram		Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, Qd		Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	3 Milligram, Bid		Not Reported
	Apo-Prednisone			S	Oral	1.3 Milligram, Bid		Not Reported
	Apo-Prednisone			S	Oral	5 Milligram, Bid		Not Reported
	Apo-Prednisone			S	Oral	50 Milligram		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram		Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram, Qwk		Not Reported

Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram, Qd	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Q6wk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Q2wk	Not Reported
	Methotrexate	S	Subcutaneous	Unk Unk, Qwk	Not Reported
	Methotrexate	S	Unknown	15 Milligram/Sq. Meter, Qwk	Not Reported
	Methotrexate	S	Unknown	15 Milligram/Sq. Meter, Q2wk	Not Reported
	Naproxen	S	Unknown		Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	50 Milligram, Bid	Not Reported
	Prednisone	S	Unknown	50 Milligram	Not Reported
	Prednisone	S	Oral	1.3 Milligram, Bid	Not Reported
	Prednisone	S	Oral	3 Milligram, Bid	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Milligram	Not Reported
	Tocilizumab	S	Unknown		Not Reported

Triamcinolone Acetonide	S	Intra-articular			Not Reported
Triamcinolone Acetonide	S	Unknown			Not Reported
Triamcinolone Hexacetonide	S	Other			Not Reported
Triamcinolone Hexacetonide	S	Unknown			Not Reported
Triamcinolone	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Milligram, Qd		Not Reported
Folic Acid	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17566294	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200321035			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Imuran /00001501/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17566419	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318563		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Pressure Fluctuation; Body Height Decreased; Contraindicated Product Administered; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Irritable Bowel Syndrome; Off Label Use; Rheumatoid Arthritis	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Infliximab, Recombinant			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Bimatoprost			C	Ophthalmic			Not Reported
	Nexium /01479302/			C	Unknown			Not Reported
	Suphedrine /00005601/			C	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported
	Tylenol /00020001/			C	Unknown			Not Reported
	Tylenol /00020001/			C				Not Reported
	Valsartan			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Esomeprazole Sodium			C	Unknown			Not Reported
	Lumigan Rc			C	Ophthalmic			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17605662	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332777		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Cataract; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Eye Disorder; Glaucoma; Hernia; Herpes Zoster; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Off Label Use; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Glumetza			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Lyrica			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Acetaminophen			C				Not Reported
	Altace			C	Unknown			Not Reported
	Asa			C				Not Reported

Codeine	C		Not Reported
D-Alpha Tocopherol	C		Not Reported
Ergocalciferol	C		Not Reported
Folic Acid	C		Not Reported
Rosuvastatin Calcium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17606950	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318841		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Red Blood Cell Sedimentation Rate Increased; Urticaria	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Remicade			S	Subcutaneous			Janssen
	Remicade			S	Unknown			Janssen
	Infliximab, Recombinant			S	Unknown			Janssen
	Infliximab, Recombinant			S	Unknown			Janssen
	Adalimumab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Sodium Aurothiomalate	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Gold	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Azathioprine	C	Unknown		Not Reported
Ciclosporin	C	Unknown		Not Reported
Minocycline	C	Unknown		Not Reported
Penicillamine	C	Unknown		Not Reported
Prednisolone	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Tocilizumab	C	Unknown		Not Reported
Actemra	C	Unknown		Not Reported
Phenylbutazone	C	Unknown		Not Reported
Tofacitinib	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17666050	EXPEDITED (15-DAY)		OT	IT-ABBVIE-20K-083-3361715-00		80 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Kaletra			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17667413	EXPEDITED (15-DAY)		LT, OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2020VAL000290			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Ventricular Tachycardia	Furosemide			S	Intravenous (not otherwise specified)	2 Df, Qd		Validus
	Azithromycin			S	Oral	250 Mg, Qd		Not Reported

Plaquenil /00072603/	S	Oral	Unk		Not Reported
Sufentanil	C		Unk		Not Reported
Perfalgan	C		Unk		Not Reported
Noradrenalin /00127501/	C		Unk		Not Reported
Midazolam	C		Unk		Not Reported
Tazocilline	C		Unk		Not Reported
Transipeg /00754501/	C		Unk		Not Reported
Potassium Chloride	C		Unk		Not Reported
Nimbex /01302502/	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17673259	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009906		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Abatacept			S	Unknown	125 Mg, Q.Wk.		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Orencia			S	Unknown	125 Mg, Q.Wk.		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Tofacitinib			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

Gabapentin	C	Oral	400 Mg, Tid		Not Reported
Tylenol Arthritis	C	Unknown	650 Mg, Qid		Not Reported
Xeljanz	C	Oral	5 Mg, Qd		Not Reported
Acetaminophen	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17695364	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-020073		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use In Unapproved Indication; Torsade De Pointes; Ventricular Arrhythmia	Azithromycin			S	Unknown	Unk		Aurobindo
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17695454	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2752444-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Drug Intolerance; Joint Swelling; Off Label Use; Product Use Issue; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Subcutaneous			Not Reported
	Imuran			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Day 1 And Day 15 Every 6 Months		Not Reported
	Actemra			S	Unknown			Not Reported

Lederle Leucovorin	S	Unknown			Not Reported
Prevnar 13	S	Intramuscular			Not Reported
Depo-Medrol With Lidocaine	S	Unknown	40-10 Mg/Ml		Not Reported
Apo-Prednisone	S	Unknown	Taper Monthly		Not Reported
Ketoprofen	S	Topical			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Leucovorin Calcium	S	Unknown			Not Reported
Azathioprine Sodium	S	Oral			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17696311	EXPEDITED (15-DAY)		OT	CA-ROCHE-2586578		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Rituximab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Amoxicillin Trihydrate;Clavulanate Potassium			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciprofloxacin Hydrochloride			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17696576	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1224670		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy; Herpes Simplex; Herpes Simplex Hepatitis; Thrombocytopenia	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Teva
	Prednisone			S	Unknown	5 Milligram Daily; Daily		Actavis
	Acetaminophen			C	Unknown	Estimated 6g		Not Reported
	Metronidazole			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17696653	EXPEDITED (15-DAY)		LT	CA-ROCHE-2585146		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Autoimmune Disorder; Cognitive Disorder; Cushing'S Syndrome; Headache; Infusion Related Reaction; Leukopenia; Muscular Weakness; Paralysis; Proteinuria; Psychotic Disorder; Therapeutic Response Decreased	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Procytox			S	Intravenous (not otherwise specified)			Not Reported
	Procytox			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Diphenhydramine			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Methylprednisolone Sodium Succinate			C	Intravenous (not otherwise specified)			Not Reported
	Methylprednisolone Sodium			C	Unknown			Not Reported

Succinate

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17696778	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584640			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Gabapentin			C				Not Reported
	Tylenol 8 Hr Arthritis Pain			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17696796	EXPEDITED (15-DAY)		OT	AU-ROCHE-2586107			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Neuropathy Peripheral; Vision Blurred	Tocilizumab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

	Lovan			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17696808	EXPEDITED (15-DAY)		HO	ES-ABBVIE-20K-144-3374580-00		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hyponatraemia	Kaletra 200/50			S	Oral			Not Reported
	Kaletra 200/50			S				Not Reported
	Dolquine			S	Oral			Not Reported
	Levofloxacino			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17696824	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585673		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Chronic Kidney Disease; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Rituximab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciprofloxacin Hydrochloride			S	Unknown			Not Reported
	Amoxicillin;Clavulanate Potassium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17696968	EXPEDITED (15-DAY)		HO	CA-ROCHE-2585153		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Celebrex			C	Unknown			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697005	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004003548			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697018	EXPEDITED (15-DAY)		OT	US-VELOXIS PHARMACEUTICALS-2018VELUS-000310			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During	Envarsus Xr			S	Transplacental	Unk		Veloxis

Pregnancy; Foetal Heart Rate Deceleration Abnormality; Lymphocytopenia Neonatal; Off Label Use; Premature Baby; Thymus Disorder	Envarsus Xr	S				Pharmaceuticals Veloxis Pharmaceuticals
	Hydroxychloroquine	S	Transplacental	Unk		Not Reported
	Hydroxychloroquine	S				Not Reported
	Azathioprine	S	Transplacental	Unk		Not Reported
	Azathioprine	S				Not Reported
	Prednisone	S	Transplacental	Unk		Not Reported
	Prednisone	S				Not Reported
	Steroids	S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697203	EXPEDITED (15-DAY)		DS, OT	CA-GLAXOSMITHKLINE-CA2020068659		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Voltaren (Diclofenac Sodium)			S	Unknown	Unk		Glaxosmithkline
	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Potassium			S	Unknown	Unk		Glaxosmithkline
	Codeine			S	Unknown	Unk		Glaxosmithkline
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Cimzia (Certolizumab Pegol)			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697218	EXPEDITED (15-DAY)		OT	ES-CIPLA LTD.-2020ES02876			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Condition Aggravated	Levofloxacin			S	Oral	500 Milligram, Qd (Per Day; 500 Mg/24h)		Cipla
	Dolquine			S	Oral	200 Milligram, Per Day (1 Comp/24h)		Not Reported
	Metronidazol [Metronidazole]			S	Oral	Unk		Not Reported
	Amoxicilina + Acido Clavulonico			S	Oral	Unk, Tid (1 Comp/8h)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697219	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226965		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Parenteral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697355	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226540			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697469	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226211		63 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Mg Daily		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697552	EXPEDITED (15-DAY)		DS, HO, OT	CA-SA-2020SA101001		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase	Hydroxychloroquine Sulfate			S				Sanofi

Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer; Unevaluable Event	Hydroxychloroquine Sulfate	S	Oral	Unk	Sanofi
	Hydroxychloroquine Sulfate	S		Unk	Sanofi
	Methotrexate	S	Subcutaneous	12.5 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	15.0 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	12 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Qw	Not Reported
	Methotrexate	S		12.5mg, Qw	Not Reported
	Methotrexate	S		10 Mg, Qw	Not Reported
	Methotrexate	S		10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	15.0 Mg Qw	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg Qw	Not Reported
	Methotrexate	S	Oral	10 Mg Qw	Not Reported
	Methotrexate	S		70.0 Mg, Qw	Not Reported
	Methotrexate	S		12.5 Mg, Qw	Not Reported
	Methotrexate	S		12.0 Mg, Qw	Not Reported
	Methotrexate	S		10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Qow	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Qw	Not Reported
	Methotrexate	S		12 Mg, Qw	Not Reported
	Alendronate Sodium	S		70 Mg, Qw	Not Reported
	Leflunomide	S			Sanofi
	Leflunomide	S	Oral		Sanofi
	Sulfasalazine	S		500 Mg	Not Reported
	Codeine	S			Not Reported
	Sodium Aurothiomalate	S	Parenteral	50 Mg, Qm	Not Reported
	Actemra	S		360 Mg	Not Reported
	Actemra	S		360 Mg	Not Reported
	Actemra	S		360 Mg, Qm	Not Reported

	Actemra	S		2.68 Mg, Q4w	Not Reported
	Enbrel	S		50 Mg	Not Reported
	Enbrel	S		25 Mg	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S		780 Mg, Qw	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Q12h	Not Reported
	Ciclosporin	C			Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697667	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1226215		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis	Leflunomide			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697668	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226208		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Methotrexate			S	Oral	25 Milligram Daily;		Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697696	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-033213		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697751	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226514		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous	12.5 Milligram Daily;		Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous	100 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17698407	EXPEDITED (15-DAY)		DE, OT	ES-FRESENIUS KABI-FK202003872		21 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Hepatitis; Hypocoagulable State; Pancreatitis Acute	Linezolid (Manufacturer Unknown)	S	Intravenous (not otherwise specified)	Unk		Fresenius Medical Care
	Amphotericin B, Liposome	S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine	S	Oral	400mg/24h		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Desconocida		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17698625	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226709			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17698783	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1226193		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Leflunomide	S	Unknown	Barr
	Methotrexate	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Aleve	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699111	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226577			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699160	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101058			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Antinuclear Antibody Positive; Arthralgia; Arthritis; Blister; Dry Mouth; Headache; Hypersensitivity Vasculitis; Hypoaesthesia; Joint Swelling; Leukopenia; Lip Swelling; Lymphadenopathy; Menorrhagia; Musculoskeletal Stiffness; Myalgia; Nausea; Parotid Gland Enlargement; Peripheral Swelling; Rheumatoid Arthritis; Sjogren'S Syndrome; Systemic Lupus Erythematosus; Vasculitis	Arava			S		Unk		Sanofi
	Colchicine			S				Not Reported
	Celecoxib			S				Not Reported
	Estradiol			S	Topical	Unk Unk, Qd		Not Reported
	Prednisone			S		50 Mg		Not Reported
	Meloxicam			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S		2 Df, Qd		Sanofi
	Salbutamol Sulfate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Belimumab			S				Not Reported
	Breo Ellipta			S	Respiratory (inhalation)			Not Reported
	Dexilant			S	Oral	60 Mg, Qd		Not Reported
	Rituximab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699175	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585119		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive	Actemra			S	Unknown			Not Reported

Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Mycophenolate Mofetil	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Amoxicillin Sodium And Clavulanate Potassium	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Ciprofloxacin	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Tridural	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699586	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585610		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling	Actemra			S	Unknown			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

Enbrel	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Lyrica	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699673	NON-EXPEDITED			US-APPCO PHARMA LLC-2083078		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699823	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226217		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Impaired Work Ability; Nasopharyngitis; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Vioxx	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Wellbutrin	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699824	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226721		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699840	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226582			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Leflunomide		S	Unknown	10 Milligram Daily;	Barr
	Methotrexate		S	Unknown		Barr
	Actemra		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Unknown		Not Reported
	Rituximab		S	Unknown		Not Reported
	Arava		C	Unknown		Not Reported
	Plaquenil[Hydroxychloroquine Phosphate]		C	Oral	400 Milligram Daily;	Not Reported
	Xeljanz		C	Oral		Not Reported
	Prednisone		C	Unknown		Not Reported
	Simponi		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699841	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226428		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Rash; Secretion Discharge; Spinal Stenosis	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous	100 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699865	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226602		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699945	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226474		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis; Therapeutic Response Decreased	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Amitriptyline Hydrochloride	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Calcium Carbonate	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Elavil	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Imitrex [Sumatriptan]	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported
	Sumatriptan Succinate	C	Unknown	Not Reported
	Tenormin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699946	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1226195			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased;	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Vascular Access Complication; White Blood Cell Count Increased	Abatacept	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Infliximab	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699990	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200428562		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Neoplasm; Injection Site Reaction; Psoriasis; Rheumatoid Arthritis	Simponi			S	Subcutaneous			Janssen
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17700384	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004003668			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Rheumatoid Arthritis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		Unk		Concordia
	Narcan			S		Unk		Not Reported
	Cyclobenzaprine Hcl			S		Unk		Not Reported
	Hydrochlorothiazide			S		Unk		Not Reported
	Wellbutrin Xl			S		Er 24h		Not Reported
	Wellbutrin Xl			S		Er 24h		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17700739	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-020169		54 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Haemolytic Anaemia; Hepatitis; Hyperbilirubinaemia; Rectal Haemorrhage	Paracetamol			S	Intravenous (not otherwise specified)	1 Gram, 3 Times A Day		Aurobindo
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram		Not Reported
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17702515	EXPEDITED (15-DAY)		LT	FR-BAUSCH-BL-2020-011521		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Venlafaxine			S	Oral			Not Reported
	Loxapine Base			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Theralene			S	Oral			Not Reported
	Paracetamol			C	Oral			Not Reported
	Nicopatch			C	Transdermal	Transdermal Device Of		Not Reported

				17.5 Mg / 10 Cm2	
	Diazepam	C	Oral		Not Reported
	Atorvastatine	C	Oral		Not Reported
	Nicotine	C	Oral		Not Reported
	Macrogol 4000	C	Oral		Not Reported
	Nebivolol	C	Oral		Not Reported
	Zopiclone	C	Oral		Not Reported
	Ramipril	C	Oral		Not Reported
	Akineton	C	Oral		Not Reported
	Ezetimibe	C	Oral		Not Reported
	Kardegic	C	Oral	Sachet Dose	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17703331	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-033234			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown	8 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17703332	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-033240			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use; Prescribed Underdose; Product Use Issue	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8.0 Milligram/Kilogram, Qmo		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17703341	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-033127			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deep Vein Thrombosis; Diarrhoea; Rash; Skin Infection; Systemic Lupus Erythematosus; Transaminases Increased; Treatment Failure	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Myochrysine			S	Intramuscular	Unk		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Pariet	C	Unknown	20 Milligram, Qd		Not Reported
	Folic Acid	C	Unknown	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17703445	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226725		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Zopiclone			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Tenofovir Disoproxil Fumarate			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17704032	DIRECT	Y	OT			32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Hydroxychloroquine 200 Mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	11433670	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-056507			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Qmo		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	400 Milligram, Qd		Not Reported
	Apo Hydroxyquine			S	Oral	400 Milligram		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, Qmo		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, Qd		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Oral	10 Milligram, Qd		Not Reported
	Leflunomide			S	Oral	10 Milligram, Qd		Not Reported
	Naprosyn [Naproxen]			S	Unknown	Unk Prn		Not Reported
	Methotrexate			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Intravenous (not	Unk		Not Reported

			otherwise specified)		
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Naproxen	S	Unknown	Unk Unk, Prn	Not Reported
	Ramipril	C	Unknown	Unk	Not Reported
	Cardio Aspirin	C	Unknown	81 Milligram	Not Reported
	Metformin	C	Unknown	Unk	Not Reported
	Lantus	C	Subcutaneous	Unk	Not Reported
	Insulin [Insulin Human]	C	Unknown	Unk	Not Reported
	Vitamin D [Ergocalciferol]	C	Unknown	Unk	Not Reported
	Calcium [Calcium Gluconate]	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk Prn	Not Reported
	Lozide [Gliclazide]	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Vitamin D Nos	C	Unknown	Unk	Not Reported
	Calcium	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	11619820	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-15K-028-1477576-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Foot Deformity; Foot Deformity; Hand Deformity; Hand	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Cyclical Frequency		Not Reported

Deformity; Hypertension; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Musculoskeletal Disorder; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Kineret	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Actonel	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Risedronate Sodium	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	11878759	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20151223430			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Confusional State; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Hospitalisation;	Simponi			S	Subcutaneous			Janssen
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Injury; Muscular Weakness; Nausea; Off Label Use; Product Label Confusion; Treatment Failure; Vomiting	Arava	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Cyclic(Every 2 Weeks) 40 Mg/0.8 Ml	Not Reported
	Orencia	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported
	Cimzia	C	Subcutaneous		Not Reported
	Enbrel	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	12791907	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2016449402		66 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Atrial Flutter; Drug Interaction	Methotrexate Sodium			S		15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		7.5 Mg, Every 10 Days		Pfizer
	Certolizumab Pegol			S		200 Mg, Every Other Week		Not Reported
	Certolizumab Pegol			S		Tapered To One Injection Every 21 Days		Not Reported
	Hydroxychloroquine			S		200 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	13091523	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP016274			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective;	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported

Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Folic Acid	S	Unknown	1 Mg, Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Hydroxychloroquine	S	Oral	Unk	Apotex
	Cetirizine	S	Unknown	10 Mg, Unk	Apotex
	Cetirizine	S	Unknown	10 Mg, Unk	Apotex
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Mg, Unk	Not Reported
	Cortisone Acetate	S	Topical	Unk	Not Reported
	Cortisone Acetate	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported

	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Reactine /00884302/	S	Unknown	Unk	Not Reported
	Certolizumab Pegol	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	13109301	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-065623		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness;	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Triamcinolone Acetonide			S	Intra-articular	Unk		Bristol Myers Squibb
	Triamcinolone Acetonide			S	Unknown			Bristol Myers Squibb
	Triamcinolone Acetonide			S	Unknown			Bristol Myers Squibb
	Triamcinolone Acetonide			S	Unknown			Bristol Myers Squibb
	Triamcinolone Acetonide			S	Oral	5 Milligram, Qd		Bristol Myers Squibb
	Triamcinolone Acetonide			S	Unknown			Bristol Myers Squibb
	Triamcinolone Acetonide			S	Unknown			Bristol Myers Squibb
	Triamcinolone Acetonide			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Subcutaneous	12.5 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk		Not Reported
	Enbrel			S	Unknown	12.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram/Sq. Meter, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	5 Milligram/Kilogram, Qd		Not Reported
	Hydroxychloroquine			S	Oral	5 Milligram, Qd		Not Reported

Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Product Use Issue; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk	Not Reported
	Infliximab	S	Unknown	5 Milligram	Not Reported
	Infliximab	S	Unknown	3 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown		Not Reported
	Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, 2 Every 1 Week	Not Reported
	Prednisone	S	Oral	5 Milligram, Bid	Not Reported
	Prednisone	S	Oral	3 Milligram, Bid	Not Reported
	Immunoglobulin [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
	Immunoglobulin [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
	Immunoglobulin [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	70 Milligram	Not Reported
	Immunoglobulin [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Naproxen	S	Unknown		Not Reported
	Apo-Prednisone	S	Oral	3 Milligram, Bid	Not Reported
	Apo-Prednisone	S	Oral	5 Milligram, Bid	Not Reported
	Apo Triamcinolone Aq	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Adalimumab	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous	50 Milligram, Qd	Not Reported

Anakinra	S	Unknown	50 Milligram, Qwk		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk		Not Reported
Tocilizumab	S	Unknown			Not Reported
Triamcinolone	S	Subcutaneous	25 Milligram, Q2wk		Not Reported
Triamcinolone	S	Unknown			Not Reported
Triamcinolone	S	Unknown			Not Reported
Triamcinolone	S	Unknown			Not Reported
Apo-Naproxen	S	Unknown	Unk		Not Reported
Apo-Naproxen	S	Unknown			Not Reported
Folic Acid	C	Unknown	Unk		Not Reported
Gammagard	S	Intravenous (not otherwise specified)	70.0 Gram		Not Reported
Gamastan	S	Intramuscular	70 Gram		Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Milligram, Qd		Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Dosage Form		Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Milligram/Kilogram, Qd		Not Reported
Naproxen Sodium	S	Unknown	Unk		Not Reported
Etanercept	S	Subcutaneous	25 Milligram(2 Every 1 Week)		Not Reported
Etanercept	S	Unknown	12.5 Milligram, Qwk		Not Reported
Triamcinolone Hexacetonide	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	13517171	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038205		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb

Arthropathy; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Actemra	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	1 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Milligram	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Bid	Not Reported
	Sulfathalidine	S	Unknown	Unk	Not Reported
	Sulfathalidine	S	Oral	1000 Milligram, Bid	Not Reported
	Sulfathalidine	S	Oral	500 Milligram	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Qd	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous	Unk	Not Reported
Tofacitinib Citrate	S	Unknown	5 Milligram, Bid	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Apo-Folic Acid	S	Unknown	5 Milligram	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Adalimumab	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Atasol [Paracetamol]	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	13667720	EXPEDITED (15-DAY)		OT	CA-ROCHE-1951961		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Bone	Rituxan			S	Intravenous (not			Not Reported

Disorder; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased				otherwise specified)	
	Cellcept [Mycophenolate Mofetil]		S	Unknown	Not Reported
	Ciclosporin		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Imuran [Azathioprine]		S	Unknown	Not Reported
	Methotrexate Sodium		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	13854282	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070658			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Orencia			S	Unknown	125 Milligram, Qwk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk Unk, Qwk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	1 Dosage Form		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Leflunomide	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk		Not Reported
Apo-Hydroxyquine	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown	Unk, Q2wk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Advil [Mefenamic Acid]	C	Unknown			Not Reported
Prednisone	C	Oral	6 Milligram, Qd		Not Reported
Prednisone	C	Oral	10 Milligram, Qd		Not Reported
Tylenol	C	Unknown	Unk		Not Reported
Dequalinium Chloride	C	Unknown	Unk		Not Reported
Mefenamic Acid	C	Unknown	Unk		Not Reported
Acetaminophen	C	Unknown			Not Reported
Advil [Ibuprofen]	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	13856327	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070350		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Drug Ineffective; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Maternal Exposure During	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	400 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Diclofenac	S	Unknown	50 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Fosamax	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
	Prednisone	S	Unknown		Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk Unk, Bid	Not Reported
	Arava	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	14757587	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009591			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Leflunomide	S	Unknown	Unk	Apotex
	Humira	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported
	Plaquenil /00072602/	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	14778860	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009970		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Inflammatory Marker Increased; Pain In Extremity; Sleep Disorder Due To A General Medical Condition	Apo-Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Subcutaneous	400 Mg, Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	14951428	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018213596		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Retinal Toxicity	Docetaxel	S	Unk, Cyclic 21-Day Cycles, 4 Cycles	Pfizer
	Hydroxychloroquine	S	Daily Dose: 7.01 Mg/Kg And Total Cumulative Dose 402 G	Not Reported
	Anastrozole	S	Unk Total Of 4 Months	Not Reported
	Cyclophosphamide	S	Unk, Cyclic 21-Day Cycles, 4 Cycles	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	15032295	EXPEDITED (15-DAY)		OT	US-SA-2018SA149938		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Off Label Use; Retinal Toxicity; Toxicity To Various Agents	Anastrozole			S				Not Reported
	Hydroxychloroquine			S		Daily Dose: 7.01 Mg/Kg		Sanofi
	Cyclophosphamide			S		21-Day Cycles		Not Reported
	Docetaxel			S		21-Day Cycles		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	15335557	EXPEDITED (15-DAY)		HO, LT, OT	MX-PFIZER INC-2018348261		67 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Bradycardia; Cardiac Failure Acute; Drug Interaction; Long Qt Syndrome; Presyncope; Sinus Bradycardia	Amiodarone Hcl			S	Oral	900 Mg, Daily (Every 24 Hours), Bolus Subsequent Dose		Pfizer
	Amiodarone Hcl			S	Unknown	200 Mg, 4x/Day		Pfizer
	Amiodarone Hcl			S	Intravenous (not otherwise specified)	300 Mg, Unk (Bolus)		Pfizer
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S		200 Mg, Daily (Every 24 Hours)		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg, 4x/Day		Not Reported
	Furosemide			S	Unknown	20 Mg, 4x/Day		Not Reported

Warfarin Sodium	S	Unknown	2.5 Mg, 4x/Day		Not Reported
Digoxin	C		Unk		Not Reported
Digoxin	C				Not Reported
Digoxin	C				Not Reported
Spironolactone	C		Unk		Not Reported
Spironolactone	C				Not Reported
Spironolactone	C				Not Reported
Metoprolol	C		Unk		Not Reported
Metoprolol	C				Not Reported
Metoprolol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	15411121	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-185070		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pruritus; Rash Maculo-Papular	Perindopril			S	Oral	Unk		Not Reported
	Perindopril			S	Unknown	Unk		Not Reported
	Repaglinide			S	Oral	()		Sun
	Plaquenil			S	Oral	200 Mg/Jour		Not Reported
	Cortancyl			S	Oral	10-20µg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	15682732	EXPEDITED (15-DAY)		DS, LT, OT	PHHY2018CA168554		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Condition Aggravated; Contraindicated Product	Diclofenac			S	Unknown	Unk		Novartis
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Leflunomide			S	Oral			Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported

Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Live Birth; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Prednisone	S	Oral	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Zyrtec-D	S	Unknown	10 Mg, Unk	Not Reported
	Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Dosage Form: Unspecified	Not Reported
	Topicort	S	Cutaneous	Unk	Not Reported
	Cirrus	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Oral	20 Mg	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous	Dosage Form: Solution	Not Reported
	Fosamax	S	Oral		Not Reported
	Plaquenil	S	Oral	400 Mg, Qd	Not Reported
	Methotrexate	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate	S	Oral	25 Mg, Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Cetirizine	S	Unknown	10 Mg, Unk	Not Reported
	Cetirizine	S			Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Dosage Form: Lyophilized Powder	Not Reported
	Apo-Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Mg, Qd	Not Reported

Apo-Prednisone	S	Oral		Not Reported
Cortisone Acetate	S	Topical	25 Mg, Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Subcutaneous	Dosage Form: Unspecified	Not Reported
Humira	S	Subcutaneous	40 Mg, 0.8ml	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Sulfathalidine	S	Oral	1000 Mg, Bid	Not Reported
Sulfathalidine	S	Oral	500 Mg, Unk	Not Reported
Tofacitinib	S	Unknown	5 Mg, Bid	Not Reported
Sulfasalazine	S	Oral	1000 Mg, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Mg, Unk	Not Reported
Xeljanz	S	Unknown	5 Mg, 2x/Day (Bid)	Not Reported
Paracetamol	S	Unknown		Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown	10 Mg	Not Reported
Reactine (Cetirizine Hydrochloride)	S			Not Reported
Stelara	S	Unknown		Not Reported
Cortisone	S	Oral		Not Reported
Methotrexate Sodium	S	Subcutaneous	25 Mg	Not Reported
Sarilumab	S	Unknown		Not Reported
Topicort	S	Unknown		Not Reported
Salazopyrin	C	Unknown		Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	16001840	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1017013		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Diclofenac Potassium			S	Unknown			Actavis

Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction; Adverse Reaction; Arthralgia; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Mobility Decreased; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Diclofenac Potassium	S	Unknown	Actavis
	Diclofenac Potassium	S	Unknown	Actavis
	Diclofenac Potassium	S		Actavis
	Acetylsalicylic Acid	S	Unknown	Not Reported
	Acetylsalicylic Acid	S	Oral	Not Reported
	Acetylsalicylic Acid	S		Not Reported
	Acetylsalicylic Acid	S		Not Reported
	Methotrexate	S	Unknown	Barr
	Methotrexate	S	Unknown	Barr
	Methotrexate	S		Barr
	Methotrexate	S		Barr
	Naproxen	S	Unknown	Teva
	Naproxen	S		Teva
	Naproxen	S		Teva
	Naproxen	S		Teva
	Sulfamethoxazole And Trimethoprim	S	Unknown	Actavis
	Sulfamethoxazole And Trimethoprim	S		Actavis
	Sulfamethoxazole And Trimethoprim	S		Actavis
	Sulfamethoxazole And Trimethoprim	S		Actavis
	Ibuprofen	S	Unknown	Actavis
	Arava	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Arava	S		Not Reported
	Aspirin	S	Oral	Not Reported
	Aspirin	S		Not Reported
	Aspirin	S		Not Reported
	Aspirin	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Enbrel	S		Not Reported
	Enbrel	S		Not Reported

Gold Injections	S	Unknown	Not Reported
Gold Injections	S		Not Reported
Gold Injections	S		Not Reported
Gold Injections	S		Not Reported
Humira (Adalimumab)	S	Subcutaneous	Not Reported
Humira (Adalimumab)	S		Not Reported
Humira (Adalimumab)	S		Not Reported
Humira (Adalimumab)	S		Not Reported
Hydroxychloroquine Sulfate Tablets	S	Unknown	Not Reported
Hydroxychloroquine Sulfate Tablets	S	Unknown	Not Reported
Hydroxychloroquine Sulfate Tablets	S	Oral	Not Reported
Hydroxychloroquine Sulfate Tablets	S		Not Reported
Motrin	S	Unknown	Not Reported
Motrin	S		Not Reported
Motrin	S		Not Reported
Motrin	S		Not Reported
Plaquenil	S	Oral	Not Reported
Plaquenil	S		Not Reported
Plaquenil	S		Not Reported
Plaquenil	S		Not Reported
Sodium Aurothiomalate Injection Bp	S	Parenteral	Not Reported
Sodium Aurothiomalate Injection Bp	S	Unknown	Not Reported
Sodium Aurothiomalate Injection Bp	S		Not Reported
Sodium Aurothiomalate Injection Bp	S		Not Reported
Vitamin C	S	Unknown	Not Reported
Vitamin C	S		Not Reported
Vitamin C	S		Not Reported
Vitamin C	S		Not Reported
Tramadol Hydrochloride	S	Unknown	Not Reported
Naprosyn	S	Unknown	Not Reported
Naprosyn	S		Not Reported

	Naprosyn	S		Not Reported
	Naprosyn	S		Not Reported
	Voltaren	S	Unknown	Not Reported
	Acetylsalicylic Acid/Clopidogrel	S	Unknown	Not Reported
	Apo-Diclofenac	S	Unknown	Not Reported
	Apo-Sulfatrim	S	Unknown	Not Reported
	Tramadol Hydrochloride	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	16047193	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020789		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Viral Upper Respiratory Tract Infection	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Leflunomide			S	Unknown			Barr
	Celebrex			S	Oral	200milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			C	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine /00072603/			C	Unknown	400 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	16397631	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-210010			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphonia; Infection Reactivation; Leishmaniasis; Sensation Of Foreign Body; Visceral Leishmaniasis; Visceral Leishmaniasis	Diclofenac			S	Unknown	Unk ()		Sun
	Hydroxychloroquine			S	Unknown	Unk ()		Sun
	Lansoprazole			C	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	Unk ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	16461090	EXPEDITED (15-DAY)		CA, DE, DS, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-211015			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Bowing Of Long Bones; Congenital Osteodystrophy; Foetal Growth Restriction; Low Birth Weight Baby; Maternal Exposure During Pregnancy; Patent Ductus Arteriosus; Premature Baby; Premature Separation Of Placenta; Right-To-Left Cardiac Shunt	Esomeprazole			S	Transplacental	20 Milligram, Daily		Sun
	Plaquenil 200 Mg, Comprime Enrobe			S	Transplacental	400 Milligram, Daily		Not Reported
	Diffu K, Gelule			S	Transplacental	1 Dosage Form, Daily		Not Reported
	Cortancyl 5 Mg, Comprime			S	Transplacental	1 Dosage Form, Daily		Not Reported
	Imurel			S	Transplacental	150 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	16544910	EXPEDITED (15-DAY)		HO, LT, OT	US-PFIZER INC-2019288608		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product	Methotrexate Sodium			S		Unk		Pfizer

Use In Unapproved Indication; West Nile Viral Infection	Methylprednisolone	S	Unk (High Dose)	Pfizer
	Rituximab	S	Unk	Pfizer
	Hydroxychloroquine	S	Unk	Not Reported
	Prednisone	S	6 Mg, Daily (Tapering Of The Dose)	Not Reported
	Mycophenolate Mofetil	S	Unk	Not Reported
	Trimethoprim Sulfamethoxazole	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	16576751	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-034879		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Acne; Appendicitis Perforated; Arthralgia; Asthenia; Bradycardia; Depressed Mood; Erythema; Fatigue; Gastrointestinal Disorder; Headache; Hypertension; Lethargy; Malaise; Nausea; Pain; Pain In Extremity; Peritonitis; Rash; Synovial Cyst	Abatacept			S	Intravenous (not otherwise specified)	500 Milligram, Qmo		Bristol Myers Squibb
	Abatacept			S	Unknown			Bristol Myers Squibb
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Cipralex [Escitalopram]			C	Unknown	Unk		Not Reported
	Estradiol			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Colace			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17165875	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151435			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Pneumocystis	Methotrexate			S	Unknown			Barr

Jirovecii Pneumonia; Pulmonary Fibrosis; Synovitis	Leflunomide	S	Unknown	400 Milligram Daily;		Barr
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine	S	Oral	2000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17188130	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201901-000131			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Photopsia; Retinal Dystrophy	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Cellcept			C		Unk		Not Reported
	Arotinolol Hydrochloride			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Takecab			C		Unk		Not Reported
	Rivotril			C		Unk		Not Reported
	Bonoteo			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17200794	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019232735			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Cholesterol Increased; Condition Aggravated;	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline

Contraindicated Product Administered; Decreased Appetite; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Hypertension; Hypoaesthesia; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Malaise; Maternal Exposure During Pregnancy; Mobility Decreased; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Folic Acid	S	Unknown	5 Milligram	Glaxosmithkline
	Folic Acid	S	Unknown	0.5 Milligram	Glaxosmithkline
	Paracetamol	S	Unknown	Unk	Glaxosmithkline
	Diclofenac Sodium	S	Unknown	Unk	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Unk	Glaxosmithkline
	Cimzia	S	Subcutaneous	400 Mg	Not Reported
	Cimzia	S			Not Reported
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S			Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	400 Mg, We, 400 Milligram, Weekly (Qw)	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira	S	Subcutaneous	Solution	Not Reported
	Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
	Xeljanz	S	Oral	5 Milligram, 2x/Week	Not Reported
	Apo Prednison	S	Unknown	Unk	Not Reported
	Apo Prednison	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Simponi	S	Subcutaneous	50 Milligram, Monthly (Qm)	Not Reported
	Simponi	S			Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Once Daily	Not Reported

			(Qd)	
Rituxan	S	Intravenous (not otherwise specified)	Solution	Not Reported
Rituxan	S	Subcutaneous	Solution	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	1000 Milligram, Once Daily (Qd)	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Phosphate	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
Hydroxychloroquine Phosphate	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
Methotrexate	S	Unknown	20 Milligram, Weekly (Qw)	Not Reported
Methotrexate	S	Oral	25 Milligram, Weekly (Qw)	Not Reported
Methotrexate	S	Oral	20 Milligram, Once Daily (Qd)	Not Reported
Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
Winpred	S	Oral	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Topicort Lp	S	Subcutaneous	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Otezla	S	Oral	3 Milligram, 2x/Day (Bid)	Not Reported
Otezla	S	Oral	3 Milligram, 2x/Day (Bid)	Not Reported

	Prednisone	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Tocilizumab	S	Subcutaneous	Unk	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Ustekinumab	S	Intravenous (not otherwise specified)	45 Milligram	Not Reported
	Topicort Lp	S	Oral	Unk	Not Reported
	Diclofenac	C	Unknown	50 Milligram, Once Daily (Qd)	Glaxosmithkline
	Desoximetasone	C	Oral	25 Milligram, Weekly (Qw)	Glaxosmithkline
	Methotrexate	C	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	C	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
	Salazopyrine	C	Oral	1 Gram, 2x/Day (Bid)	Not Reported
	Tofacitinib Citrate	C	Oral	5 Milligram, Weekly (Qw)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17215818	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1952857US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss	Actonel			S	Unknown	35 Mg, Q Week		Allergan
	Actonel			S	Unknown	35 Mg, Q Week		Allergan
	Actonel			S	Unknown	35 Mg, Q Week		Allergan
	Actemra			S	Subcutaneous	Unk Mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Anakinra			S	Subcutaneous	100 Mg		Not Reported
	Anakinra			S	Subcutaneous	100 Mg		Not Reported
	Apo-Leflunomide			S	Oral	20 Mg, Unk		Not Reported

Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Arava	S	Oral	20 Mg, Qd	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	50 Mg	Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Mg, Q2weeks	Not Reported
	Hydroxychloroquine	S	Unknown	300 Mg, Qd	Not Reported
	Hydroxychloroquine	S	Oral	20 Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Mg	Not Reported
	Leflunomide	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown	300 Mg, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17425099	EXPEDITED (15-DAY)		HO, OT	US-GLAXOSMITHKLINE-US2020023487		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Anaemia; Dizziness; Haemolytic Uraemic Syndrome; Hypotension; Nausea; Product Dose Omission; Renal Injury;	Benlysta			S	Intravenous (not otherwise specified)	Unk Unk, We		Glaxosmithkline
	Cipro			S	Unknown	Unk		Glaxosmithkline
	Plaquenil			S	Unknown	Unk		Not Reported

Urinary Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17543214	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-020534			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Alendronate Sodium			S	Oral	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Topical	25 Milligram		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported

Hydroxychloroquine	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown		Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17605652	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332789		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration 2.0 Years		Janssen

Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Certolizumab Pegol	S	Subcutaneous		Not Reported
	Certolizumab Pegol	S	Unknown		Not Reported
	Ciclosporin	S	Vaginal		Not Reported
	Ciclosporin	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Pregabalin	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported
	Lyrica	S	Vaginal		Not Reported
	Piroxicam	C			Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17623406	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200342133			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Joint Swelling; Rheumatoid Arthritis; Synovitis; X-Ray Abnormal	Simponi			S	Subcutaneous			Janssen
	Cimzia			S	Subcutaneous	Single Use		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	5 Years		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	7 Months		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17623534	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340450		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Alopecia; Arthropathy; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Glossodynia; Hand Deformity; Nausea; Oedema; Off Label Use; Pain; Pemphigus; Prescribed Overdose;	Simponi			S	Subcutaneous			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Rheumatoid Arthritis; Synovitis; Systemic Lupus Erythematosus; Underdose; Vomiting	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Naprosyn /00256201/	C	Unknown	Not Reported
	Naprosyn /00256201/	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17641316	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029045			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Fosamax			S	Oral	Unk		Not Reported

Fosamax	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Methotrexate	S	Unknown			Not Reported
Phthalylsulfathiazole	S	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17666360	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009894		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Rash; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

Sulfasalazine	S	Unknown	300 Mg, Qd		Not Reported
Xeljanz	C	Oral	5.0 Mg, Bid		Not Reported
Magnesium	C	Unknown	Unk		Not Reported
Methotrexate	C	Unknown	Unk		Not Reported
Calcium	C	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	C	Unknown	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17701054	EXPEDITED (15-DAY)		CA, DS, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-244979			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chondrodystrophy; Chondropathy; Dysmorphism; Low Birth Weight Baby; Maternal Exposure During Pregnancy	Paracetamol		Y	S	Transplacental	Unk ()		Ohm Lab
	Keppra			S	Transplacental	Unk ()		Not Reported
	Trileptal			S	Transplacental	Unk ()		Not Reported
	Plaquenil			S	Transplacental	Unk ()		Not Reported
	Kaleorid			C	Transplacental	Unk		Not Reported
	Orocal D3			C	Transplacental	Unk		Not Reported
	Speciafoldine			C	Transplacental	Unk ()		Not Reported
	Cortancyl			C	Transplacental	Unk ()		Not Reported
	Diffu-K			C	Transplacental	Unk ()		Not Reported
	Actonel			C	Transplacental	Unk ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17701285	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-244571		31 YR	Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17701299	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-244572		42 YR	Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17701322	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-019746			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Systemic Lupus Erythematosus	Celecoxib Capsules			S	Oral	200 Milligram, Two Times A Day		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17701422	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-020069		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Risperidone			S	Oral	2 Milligram, Once A Day		Aurobindo
	Effexor			S	Oral	150 Milligram, Daily		Not Reported
	Plaquenil			S	Oral	600 Milligram, Daily		Not Reported
	Acebutolol			C	Oral	400 Milligram, Once A Day		Not Reported

Amlodipine	C	Oral	10 Milligram, Once A Day		Not Reported
Clomipramine Hydrochloride	C	Oral	150 Milligram, 1 Month		Not Reported
Enoxaparin	C	Subcutaneous	4000 International Unit, Daily		Not Reported
Hydrochlorothiazide	C	Oral	25 Milligram, Once A Day		Not Reported
Macrogol 4000	C	Oral	2 Dosage Form, Daily		Not Reported
Nicardipine Hydrochloride	C	Oral	60 Milligram, Daily		Not Reported
Oxazepam	C	Oral	100 Milligram, Once A Day		Not Reported
Zopiclone	C	Oral	7.5 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17701432	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-020070		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Venlafaxine			S	Oral	225 Milligram, Once A Day		Aurobindo
	Loxapine			S	Oral	155 Milligram, Once A Day		Not Reported
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported
	Theralene			S	Oral	50 Milligram, Once A Day		Not Reported
	Akineton			C	Oral	4 Milligram		Not Reported
	Atorvastatine			C	Oral	40 Milligram, Once A Day		Not Reported
	Diazepam			C	Oral	10 Milligram, Once A Day		Not Reported
	Ezetimibe			C	Oral	10 Milligram, Once A Day		Not Reported
	Kardegic			C	Oral	75 Milligram, Once A Day		Not Reported
	Macrogol 4000			C	Oral	Unk		Not Reported
	Nebivolol			C	Oral	7.5 Milligram, Once A Day		Not Reported
	Nicopatch			C	Transdermal	7 Milligram, Once A Day		Not Reported
	Nicotine			C	Oral	12 Milligram, Once A Day		Not Reported
	Paracetamol			C	Oral	1 Gram, Once A Day		Not Reported
	Ramipril			C	Oral	1.25 Milligram, Once A Day		Not Reported

Zopiclone	C	Oral	7.5 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17702414	EXPEDITED (15-DAY)		HO, LT, OT	ES-SA-2020SA105860		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Thrombocytopenia	Enoxaparin Sodium			S	Subcutaneous	40 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Metamizole Salt Not Specified			S	Intravenous (not otherwise specified)	2 G, Q8h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17702747	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031352			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

Methotrexate	S	Oral	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Oral	1 Gram, Bid		Not Reported
Tofacitinib Citrate	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17702855	EXPEDITED (15-DAY)			CA-SA-2020SA102454			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pregnancy	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Leflunomide			S	Unknown	10 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	, 20-12.5 Mg;Unk		Not Reported
	Sulfasalazine			S	Unknown	2 G		Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17702988	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226290		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Other	400 Milligram Daily; Route Of Administration: Sng		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703170	EXPEDITED (15-DAY)		OT	GB-ALKEM LABORATORIES LIMITED-GB-ALKEM-2020-01206			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ear Infection; Respiratory Tract Infection; Secondary Immunodeficiency; Urinary Tract Infection	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Mycophenolate Mofetil			S				Alkem
	Azathioprine			S	Unknown	Unk		Alkem
	Azathioprine			S				Alkem
	Hydroxychloroquine			S		Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703204	EXPEDITED (15-DAY)		OT	DE-HIKMA PHARMACEUTICALS USA INC.-DE-H14001-20-511		42 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis; Erythema Nodosum; Herpes Dermatitis; Herpes Simplex; Immune Reconstitution Inflammatory Syndrome; Lymphoedema; Mass; Nodule; Panniculitis; Papilloma Viral Infection; Periorbital Oedema; Periorbital Swelling	Ceftriaxone			S	Unknown			Hikma
	Ceftriaxone Sodium			S	Unknown			Not Reported
	Streptomycin			S	Unknown			Not Reported
	Prednisone			S	Unknown	()		Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cotrimoxazole			S	Unknown			Not Reported
	Sulfamethoxazole And Trimethoprim			S	Unknown			Not Reported
	Sulfamethoxazole And Trimethoprim			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Azathioprine	S	Unknown	Not Reported
	Acyclovir	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703265	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1226288		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Drug Interaction; Tachyarrhythmia	Hidroxicloroquina Sulfato (2143su)			S	Oral	200 Mg		Teva
	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Tocilizumab (8289a)			C	Intravenous (not otherwise specified)			Not Reported
	Ceftriaxona (501a)			C	Intravenous (not otherwise specified)	1 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703315	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004003552			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sjogren'S Syndrome	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703318	EXPEDITED (15-DAY)		DE	MX-ADVANZ PHARMA-202004002571			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atypical Pneumonia; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703402	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-020221		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pulmonary Embolism	Paracetamol	S	Oral	4 Gram, Once A Day	Aurobindo
	Nefopam Hydrochloride	S	Oral	80 Milligram, Once A Day	Not Reported
	Augmentin	S	Intravenous (not otherwise specified)	3 Gram, Once A Day	Not Reported
	Plaquenil	S	Oral	400 Milligram, Once A Day	Not Reported
	Amlor	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Colchimax (Colchicine/Papaver Somniferum Powder/Tiemonium Methylsulphate)	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Arimidex	S	Oral	1 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703409	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-020223		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Sinus Bradycardia	Levofloxacin			S	Intravenous (not otherwise specified)	1000 Milligram		Aurobindo
	Plaquenil			S	Oral			Not Reported
	Zithromac			S	Oral	500 Milligram, Once A Day		Not Reported
	Zyvoxid			C	Intravenous (not otherwise specified)	1200 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703414	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-020196		81 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Condition Aggravated	Amoxicillin+Clavulanic Acid			S	Oral	1 Comp/8h		Aurobindo
	Levofloxacin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Metronidazole			S	Oral	Unk		Aurobindo
	Dolquine			S	Oral	200 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703479	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3376441-00		72 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Hypertransaminasaemia; Off Label Use	Kaletra			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Zitromax Avium			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703559	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004003551			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Hypertension; Multiple Organ Dysfunction Syndrome; Off Label Use; Paralysis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703593	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004003545			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neoplasm Malignant; Papilloma Viral Infection	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703666	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1226209		95 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Sudden Death	Quetiapina (1136a)			S	Oral	25 Mg		Teva
	Levofloxacino (2791a)			S	Intravenous (not otherwise specified)	500 Mg		Teva

Hidroxicloroquina Sulfato (2143su)	S	Oral	200 Mg		Teva
Risperidona (7201a)	S	Oral	1 Mg		Actavis
Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid	S	Oral	2 Dosage Forms		Not Reported
Losartan (7157a)	C	Oral	50 Mg		Not Reported
Clindamicina Hidrocloruro (616ch)	C	Intravenous (not otherwise specified)	600 Mg		Not Reported
Lorazepam (1864a)	C	Oral	1 Mg		Not Reported
Furosemida (1615a)	C	Oral	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703680	EXPEDITED (15-DAY)		OT	FI-ADVANZ PHARMA-E2B_00008842			Unknown	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lymphopenia; Thrombocytopenia	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703729	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004003540			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chemotherapy	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703911	EXPEDITED (15-DAY)		HO	FR-ADVANZ PHARMA-202004003504			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Disease Progression;	Hydroxychloroquine			S	Oral	200 Mg, (Film Coated Tablet)		Concordia

Lymphopenia	Repaglinide	C	Unk	Not Reported
	Metformin	C	Unk	Not Reported
	Glimepiride	C	Unk	Not Reported
	Bisoprolol	C	Unk	Not Reported
	Perindopril	C	Unk	Not Reported
	Kardegic	C	Unk	Not Reported
	Levocetirizine	C	Unk	Not Reported
	Finasteride	C	Unk	Not Reported
	Pregabaline	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17704031	DIRECT	Y	DE			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection	Hydroxychloroquine 400 Mg			S	Oral			Not Reported
	Hydroxychloroquine 200 Mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17704205	EXPEDITED (15-DAY)		HO, OT	LT-ADVANZ PHARMA-GSH201609-004911			Unknown	LTU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Body Temperature Increased; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia; Hepatic Enzyme Increased; Inflammatory Marker Increased; Rash Maculo-Papular	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17704214	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202004003538			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Drug Intolerance	Hydroxychloroquine			S	Unknown	400 Mg		Concordia
	Leflunomide			S	Unknown	20 Mg		Not Reported
	Arava			S	Unknown	10 Mg		Not Reported
	Kevzara			S	Unknown	Unk		Not Reported
	Sarilumab Autoinjector			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Xeljanz Xr			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported
	Pregabalin			C		Unk		Not Reported
	Vitamin B12 [Vitamin B12 Nos]			C		Unk		Not Reported
	Salazopyrin			C		Unk		Not Reported
	Codeine			C		Unk		Not Reported
	Prednlsone			C		Unk		Not Reported
	Synthroid			C		Unk		Not Reported
	Cortisone			C		Unk		Not Reported
	Dexilant			C		Unk		Not Reported
	Vitamin D [Vitamin D Nos]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17704217	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202004003541			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neuropathy Peripheral	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Concordia
	Hydroxychloroquine			S	Unknown	1000 Mg, Bid		Concordia

	Orencia	S	Unknown	Unk		Not Reported
	Losec	C				Not Reported
	Clopidogrel	C		Unk		Not Reported
	Rosuvastatin	C				Not Reported
	Perindopril	C				Not Reported
	Nitrospray	C				Not Reported
	Methotrexate	C		Unk		Not Reported
	Sulfasalazine	C				Not Reported
	Amlodipine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17704377	EXPEDITED (15-DAY)		OT	IN-LUPIN PHARMACEUTICALS INC.-2020-01788		51 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Neurosensory; Ototoxicity	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Prednisolone			C	Unknown	40 Milligram, Qd		Not Reported
	Prednisolone			C	Unknown	5 Milligram, Qd (Gradually Tappered)		Not Reported
	Prednisolone			C	Unknown	10 Milligram, Qd (Dose Increased)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705063	NON-EXPEDITED			US-PFIZER INC-2020159965		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Sulfasalazine			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Meloxicam			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705271	EXPEDITED (15-DAY)		DE	ES-JNJFOC-20200419053		95 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Risperdal			S	Oral			Janssen
	Levofloxacin			S	Intravenous (not otherwise specified)			Not Reported
	Quetiapine			S	Oral			Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported
	Kaletra			S	Oral	200/50 Mg		Not Reported
	Lorazepam			C	Oral			Not Reported
	Furosemida /00032601/			C	Oral			Not Reported
	Losartan			C	Oral			Not Reported
	Clindamicina /00166002/			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705322	DIRECT		DE, HO			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Dysfunction; Cardio-Respiratory Arrest; Fall; Hallucination, Visual; Pulmonary Hypertension	Hydroxychloroquine			S	Oral	Quantity:1 Tablet(S);		Not Reported
	Triamcinolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705467	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100979		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red	Hydroxychloroquine Sulfate			S				Sanofi
	Sulfasalazine			S				Not Reported
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S				Not Reported

Blood Cell Sedimentation Rate Abnormal; Synovitis	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Humira	S	Subcutaneous	40 Mg, Solution Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	750 Mg	Not Reported
	Rituximab	S	Intravenous drip	2000 Mg	Not Reported
	Xeljanz	S			Not Reported
	Xeljanz	S	Oral	50 Mg, Bid (2 Every 1 Day)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705685	EXPEDITED (15-DAY)		DE	FR-PFIZER INC-2020162444		62 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use In Unapproved Indication; Sudden Death	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705686	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020162461		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Drug Interaction; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Other	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Other	Unk		Not Reported
	Primperan			S	Intravenous drip	30 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705727	EXPEDITED (15-DAY)		HO	CA-SAOL THERAPEUTICS-2020SAO00108			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein	Rho D Immune Globulin			S				Saol Therapeutics
	Actemra			S	Intravenous (not	8.0 Mg/Kg, 1x/Month		Not Reported

Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure			otherwise specified)		
	Arava	S		20 Mg	Not Reported
	Benzalkonium Chloride	S			Not Reported
	Benzalkonium Chloride/ Diphenhydramine Hydrochloride/ Phenylephrine Hy	S			Not Reported
	Boric Acid	S			Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Disodium Edetate	S			Not Reported
	Enbrel	S	Subcutaneous	40 Mg, 1x/Week	Not Reported
	Gold	S			Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Hydroxychloroquine	S			Not Reported
	Hydroxychloroquine Sulfate	S		200 Mg, 2x/Day	Not Reported
	Methotrexate	S	Oral	15 Mg, 1x/Week	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phenylephrine Hydrochloride	S			Not Reported
	Rituximab	S			Not Reported
	Simponi	S			Not Reported
	Sodium Borate	S			Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Tofacitinib Citrate	S		10 Mg, 2x/Week	Not Reported
	Tofacitinib Citrate	S		5 Mg, 2x/Week	Not Reported
	Tofacitinib Citrate	S	Subcutaneous	5 Mg, 2x/Week	Not Reported
	Celebrex	C	Oral	400 Mg	Not Reported
	Ibuprofen	C	Oral	400 Mg	Not Reported
	Lipitor	C	Oral	10 Mg, 1x/Day	Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705848	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-		73 YR	Female	ESP

3376750-00

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Ageusia; Anosmia; Condition Aggravated; Nausea; Off Label Use; Oxygen Saturation; Productive Cough; Pyrexia	Kaletra			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ceftriaxone			S	Unknown			Not Reported
	Heparin			C		Prophylactic Dose		Not Reported
	Tocilizumab			C				Not Reported
	Methylprednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705929	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR-1226300		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Loss Of Consciousness; Malaise; Ventricular Extrasystoles	Azithromycine Anhydre			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Lovenox			C	Oral			Not Reported
	Paracetamol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705944	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226289		28 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not	2 Gram Daily;		Not Reported

				otherwise specified)			
	Ceftriaxona (501a)		S				Not Reported
	Paracetamol (12a)		S	Intravenous (not otherwise specified)	1 Gram Every 8 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706122	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-032305			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Folic Acid			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

	Pseudoephedrine Hydrochloride		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706318	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020162376			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Nightmare; Off Label Use; Product Use In Unapproved Indication; Psychomotor Hyperactivity	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706431	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226597		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported

	Aspirin [Acetylsalicylic Acid]		C	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe		C	Subcutaneous	Not Reported
	Cymbalta		C	Unknown	Not Reported
	Hydromorphone		C	Unknown	Not Reported
	Remicade		C	Intravenous (not otherwise specified)	Not Reported
	Synthroid		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706432	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226715			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706435	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226417		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia;	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous	15 Mg, 1 Every 1 Week		Barr

Rash; Toxicity To Various Agents; Visual Impairment	Actemra	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	1 Milligram Daily;	Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706545	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226712			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706575	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226588		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Leflunomide	S	Oral	Barr
	Methotrexate	S	Unknown	Barr
	Methotrexate	S	Unknown	Barr
	Methotrexate	S	Unknown	Barr
	Methotrexate	S	Subcutaneous	Barr
	Methotrexate	S	Unknown	Barr
	Methotrexate	S	Subcutaneous	Barr
	Alendronate	S	Oral	Actavis
	Codeine	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Myochrysine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706578	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226794			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Infection; Joint Swelling; Lower Respiratory Tract Infection; Nausea;	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr

Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Arthritis	Methotrexate	S	Subcutaneous		Barr
	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Diclofenac Sodium/Misoprostol	S	Unknown	100 Milligram Daily;	Not Reported
	Diclofenac Sodium/Misoprostol	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Vitamin D3	C			Not Reported
	Imuran [Azathioprine]	C			Not Reported
	Gold	C			Not Reported
	Arthrotec	C	Unknown	100 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706582	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226586		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Asa			C	Unknown			Not Reported
	Clonazepam			C	Oral			Not Reported
	Desipramine			C	Oral			Not Reported
	Gabapentin			C	Oral			Not Reported
	Nitroglycerin			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706588	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226758		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Leflunomide			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Folic Acid	C		Not Reported
	Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706589	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1226786			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Off Label Use; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Leflunomide			S	Unknown			Barr
	Leflunomide			S				Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Intravenous (not otherwise specified)			Not Reported

	Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706590	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226708		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Leflunomide			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706609	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226204		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Alendronate Sodium			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Myochrysine			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown	2000 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706648	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226631			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported

	Apo-Prednisone	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Reactine (Cetirizine)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706659	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226499			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mood Altered	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706688	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226489			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Headache; Tremor	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Oral	2.5 Milligram Daily;		Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Oral			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Pantoprazole			C	Oral	40 Milligram Daily;		Not Reported
	Tenofovir Disoproxil			C	Unknown			Not Reported
	Tenofovir Disoproxil			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Zopiclone			C	Unknown	7.5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706692	EXPEDITED (15-DAY)		OT	NVSC2020DE069507		58 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Febrile Neutrophilic Dermatosis; Drug Interaction; Off Label Use; Product Use In Unapproved Indication	Ramipril	S	Oral	Unk		Not Reported
	Amlodipine	S	Unknown	Unk		Novartis
	Esomeprazole	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Boswellia Serrata Extract	S	Unknown	Unk		Not Reported
	Thyroxine	C	Unknown			Not Reported
	Levothyroxine Sodium	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706698	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1226415		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706704	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226800		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; Drug Ineffective; Fall; Fatigue; Femur Fracture; Intentional Product Use Issue; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706706	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226401			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Liver Injury	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706708	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226422			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Neutropenia; White Blood Cell Count Decreased	Leflunomide	S	Unknown		Barr
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Enbrel	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706711	EXPEDITED (15-DAY)		DE, LT	NVSC2020CA108434		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S				Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Sulfasalazine			S	Unknown	500 Mg		Not Reported
	Sulfasalazine			S				Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S				Not Reported

Gold	S	Unknown	Unk	Not Reported
Gold	S			Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S			Not Reported
Marijuana	S	Unknown	Unk	Not Reported
Minocycline	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S			Not Reported
Oxycodone	S	Unknown	10 Mg	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S			Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Sodium Aurothiomalate	S			Not Reported
Xeljanz	S	Oral	2 Df, Qd	Not Reported
Leflunomida	S	Unknown		Not Reported
Minocycline Hydrochloride	S	Unknown		Not Reported
Lyrica	C	Unknown	Unk	Not Reported
Kineret	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706712	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226575		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Clostridium Difficile Infection; Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Myochrysine			S	Unknown			Not Reported

Enbrel	C	Unknown			Not Reported
Gold	C	Unknown			Not Reported
Humira	C	Unknown			Not Reported
Meloxicam	C	Unknown			Not Reported
Methotrexate	C	Unknown	20 Milligram Daily;		Not Reported
Orencia	C	Unknown			Not Reported
Orencia	C	Unknown			Not Reported
Remicade	C	Unknown			Not Reported
Sulfasalazine	C	Unknown			Not Reported
Sulfasalazine	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706716	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226199		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706718	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226485		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Nodule	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706719	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226393			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Drug Ineffective; Joint Swelling	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Amitriptyline			C				Not Reported
	Cefazolin			C				Not Reported
	Clindamycin			C				Not Reported
	Prednisone			C				Not Reported
	Tylenol W/Codeine No.3			C				Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706723	EXPEDITED (15-DAY)		LT	NVSC2020CA108426		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased;	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported

Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Minocycline	S	Unknown	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown		Not Reported
	Oxycodone	S	Unknown	10.0 Mg	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S			Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S			Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S			Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S			Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hidroxicloroquina	S	Unknown		Not Reported
	Hidroxicloroquina	S			Not Reported
	Marijuana	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S			Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S			Not Reported
	Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sodium Aurothiomalate	S			Not Reported

	Sulfasalazine		S	Unknown	500 Mg	Not Reported
	Sulfasalazine		S			Not Reported
	Xeljanz		S	Oral	Unk (2 Every 1 Days)	Not Reported
	Kineret		C	Unknown	Unk	Not Reported
	Lyrica		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706744	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226225			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Transaminases Increased	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706821	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226617		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Fatigue; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Swelling; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown	20 Mg		Barr
	Methotrexate			S	Unknown	12.5 Mg, 4 Every 1 Week		Barr
	Methotrexate			S	Unknown	20 Mg, 4 Every 1 Week		Barr
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Simponi	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Rituxan	C	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706824	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226496		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Leflunomide			S	Unknown	200 Milligram Daily;		Barr
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sulfasalazine	S	Oral		Not Reported
	Tylenol	S	Unknown		Not Reported
	Hydromorphone Hydrochloride	C			Not Reported
	Meloxicam	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Synthroid	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706884	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226629		55 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706888	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226486		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis;	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

Scar; Vomiting	Sulfasalazine	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Arava	S	Oral	Not Reported
	Actemra	S	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Aspirin[Acetylsalicylic Acid]	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706960	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226817			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Perforation; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706962	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1227023			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide	S	Unknown		Barr
	Naproxen	S	Unknown		Teva
	Prednisone	S	Unknown		Actavis
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Folic Acid	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706969	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226569			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706970	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226578		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Alendronate			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip	2000 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17707004	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226718		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Alendronic Acid			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip	2000 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Ciclosporin			C	Unknown	150 Milligram Daily;		Not Reported

	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17707009	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226580			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Bifidobacterium Bifidum			C	Unknown			Not Reported
	Loperamide			C	Oral			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17707545	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226576			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Humira			S	Subcutaneous				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17707742	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226778		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash	Leflunomide			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone Acetate			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17707753	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1225340			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Rheumatoid Arthritis	Cyclobenzaprine Hcl 5 Mg Tablet		S	Unknown		Actavis
	Xeljanz		S	Oral	10 Milligram Daily; 60/Btl	Not Reported
	Narcan 4 Mg Spray		S	Unknown	Spray	Not Reported
	Plaquenil 200 Mg Tablet		S	Unknown		Not Reported
	Hydrochlorothiazide 25 Mg Tablets		S	Unknown		Not Reported
	Wellbutrin Xl Tab Er		S	Unknown	150 Milligram Daily; Er	Not Reported
	Wellbutrin Xl Tab Er		S	Unknown	300 Milligram Daily; Er	Not Reported
	Prednisone 10 Mg Tablet		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17707828	EXPEDITED (15-DAY)		HO	ES-009507513-2004ESP006461		73 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Haemorrhage; Hepatitis Acute	Ertapenem Sodium			S	Intravenous (not otherwise specified)	1 G Day		Merck
	Piperacillin Sodium (+) Tazobactam Sodium			S	Intravenous (not otherwise specified)	C/24 H		Not Reported
	Azithromycin			S	Oral	500 Mg Per Day		Not Reported
	Dolquine			S	Oral	400 Mg Per Day		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17707836	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226792			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Infection; Leukopenia; Neutropenia; Therapeutic Response Decreased	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17707886	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226781		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Leflunomide			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17710887	DIRECT		DE			50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Myocardial Infarction	Hydroxychloroquine	Y		S				Not Reported
	Biotin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	14994173	EXPEDITED (15-DAY)		OT	US-ACCORD-067914		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Retinal Toxicity; Visual Field Defect	Anastrozole			S				Accord
	Docetaxel			S		Four 21-Day Cycles		Not Reported
	Hydroxychloroquine			S		Hcq Daily Dose: 7.01		Not Reported

				Mg/Kg And Total Cumulative Dose 402 G	
	Cyclophosphamide/Cyclophosphamide Monohydrate		S	21-Day Cycles	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	15611218	EXPEDITED (15-DAY)		HO, OT	IT-ACCORD-091251		15 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Drug Intolerance; Gastrointestinal Disorder; Haematuria; Headache; Hypertransaminasaemia; Nausea; Pneumonia; Proteinuria; Pyrexia; Respiratory Symptom	Mycophenolic Acid			S				Accord
	Tacrolimus			S				Accord
	Hydroxychloroquine			S				Not Reported
	Rituximab			C				Not Reported
	Cyclophosphamide/Cyclophosphamide Monohydrate			C		Pulse		Not Reported
	Methylprednisolone			C				Not Reported
	Amphotericin B/Amphotericin B/Liposome			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	16739695	EXPEDITED (15-DAY)		OT	DE-ACCORD-152822			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Ramipril			S	Oral	1 Df Bid (1-0-1), 2x/Day		Accord
	Pregabalin			S	Unknown	1 Df, Tid (1-1-1)		Not Reported
	Sildenafil/Sildenafil Citrate			S	Unknown			Not Reported
	Ambrisentan			S				Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1-0-1), 40 Mg Per Day, 20 Mg Bid		Not Reported
	Eliquis			S	Unknown	1 Df, Bid (1-0-1), 5 Mg Per Day, 2.5 Mg Bid,		Not Reported
	Roactemra			S		162 Mg, Qw		Not Reported
	Spasmolyt			S		15 Mg, Qd (1-0-0),Also Received 30 Mg (0 -0 -1)		Not Reported

	Omeprazole	S	Oral	1 Df, Bid (1-0-1), 40 Mg Per Day, 20 Mg, Bid	Not Reported
	Tocilizumab	S	Subcutaneous		Not Reported
	Volibris	S	Oral	1 Dosage Form, Qd	Not Reported
	Lyrica	S	Unknown	100 Mg, Tid	Not Reported
	Spasmolyt	S		30 Mg (0 -0 -1)	Not Reported
	Tocilizumab	S	Subcutaneous		Not Reported
	Ramipril	S	Unknown		Accord
	Quensyl	S	Unknown	1 Df, Bid (1 - 0 - 1)	Not Reported
	Volibris	S	Oral		Not Reported
	Trospium Chloride	S		30 Mg (0 -0 -1)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	17678870	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202004002849			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Coma; Condition Aggravated; Off Label Use	Hydroxychloroquine			S	Oral	200 Mg, Qd, Film Coated Tablet		Concordia
	Hydroxychloroquine			S	Oral	Unk		Concordia
	Midazolam			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Morphine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	17707971	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004003553			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Eye Disorder; Off Label Use; Product Dose Omission	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	17708013	EXPEDITED (15-DAY)		OT	IT-ADVANZ PHARMA-GSH201610-005089			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Dilatation Atrial	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Concordia
	Methotrexate			S	Unknown	7.5 Mg Every 10 Days		Not Reported
	Methotrexate			S		Reduction In The Dose Of Methotrexate 7.5 Mg Every 10 Days		Not Reported
	Certolizumab Pegol			S	Unknown	200 Mg Every Other Week		Not Reported
	Certolizumab Pegol			S	Unknown	200 Mg Every Other Week		Not Reported
	Bromazepam			C				Not Reported
	Bromazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	17708019	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-MAPI_00011385			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Function Test Abnormal; Cardiotoxicity; Ejection Fraction Decreased; Product Use In Unapproved Indication; Sinus Tachycardia; Tachycardia; Ventricular Hypokinesia	Hydroxychloroquine			S	Unknown	600 Mg, Qd		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Doxycycline			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	17708183	EXPEDITED (15-DAY)		DS, OT	US-ADVANZ PHARMA-202004004057			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	17708184	EXPEDITED (15-DAY)		DS, OT	US-ADVANZ PHARMA-202004003665			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2020	17574299	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-GSH201806-002062			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Off Label Use; Retinal Toxicity; Toxicity To Various Agents	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	7.01 Mg/Kg, Qd (Total Cumulative Dose 402 G)		Concordia
	Cyclophosphamide			S	Unknown	21-Day Cycles		Not Reported
	Docetaxel			S	Unknown	21-Day Cycles		Not Reported
	Anastrozole			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2020	17708342	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA108440			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis;	Ilaris			S	Subcutaneous			Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported

Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Thrombosis; Urticaria	Minocycline	S	Unknown		Not Reported
	Minocycline Hydrochloride	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	500 Mg	Not Reported
	Sulfasalazine	S			Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S			Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S			Not Reported
	Gold	S	Unknown		Not Reported
	Gold	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported
	Marijuana	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported
	Oxycodone	S	Unknown	10 Mg	Not Reported
	Plaquenil	S	Oral		Not Reported
	Plaquenil	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S			Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Xeljanz	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2020	17708442	EXPEDITED (15-DAY)		OT	NVSC2020CA111350			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Bursitis; Chronic Obstructive Pulmonary Disease; Drug Hypersensitivity; Hypothyroidism; Obesity; Osteoarthritis; Osteopenia; Synovitis; Therapeutic Product Effect Incomplete	Cosentyx			S	Unknown	Unk Unk, Unknown		Novartis
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2w		Not Reported
	N-(3-Chloroallyl)Hexaminium Chloride			S	Unknown	Unk		Not Reported
	Penicillin G			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Qmo		Not Reported
	Stelera			S	Unknown	Unk, 1 Every 8 Weeks		Not Reported
	Stelera			S	Subcutaneous	Unk		Not Reported
	Cetirizine			C	Unknown	10 Mg, Bid		Not Reported
	Enbrel			C	Unknown	50 Mg, Qw		Not Reported
	Lasix			C	Unknown	40 Mg, Qmo		Not Reported
	Montelukast			C	Unknown	10 Mg, Qd		Not Reported
	Synthroid			C	Unknown	75 Mg, Qd		Not Reported
	Terbutaline Sulfate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2020	17708667	EXPEDITED (15-DAY)		OT	NVSC2020CH106927		33 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia; Product Use In Unapproved Indication; Therapy Non-Responder	Mycophenolate Mofetil			S	Unknown	2 G, Qd		Novartis
	Methotrexate			S	Unknown	Unk Ukn		Not Reported
	Azathioprine			S	Unknown	Unk Ukn		Not Reported

Hydroxychloroquine	S	Unknown	Unk Ukn		Not Reported
Infliximab	S	Unknown	Unk Ukn		Not Reported
Prednisone	S	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2020	17709300	EXPEDITED (15-DAY)		DE	FR-AUROBINDO-AUR-APL-2020-020616			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Off Label Use	Azithromycin			S	Unknown	Unk		Aurobindo
	Azithromycin			S				Aurobindo
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2020	17711723	DIRECT					28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tachycardia	Hydroxychloroquine	Y		S	Oral			Not Reported
	Propranolol			C				Not Reported
	Valium			C				Not Reported
	Prilosec			C				Not Reported
	Pristiq			C				Not Reported
	Norethidrone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	13058853	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015743		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush;	Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	8 Mg, Unk		Not Reported

Hypertension; Joint Swelling; Off Label Use; Synovitis; Therapeutic Response Decreased	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Humira	S	Unknown	40 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Rituximab;Vorhyaluronidase Alfa	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Calcium Carbonate	C	Unknown	Unk	Not Reported
	Elavil /00002202/	C	Unknown	Unk	Not Reported
	Hydrochlorothiazide	C	Unknown	Unk	Not Reported
	Imitrex /01044801/	C	Unknown	Unk	Not Reported
	Lyrica	C	Unknown	Unk	Not Reported
	Premarin	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Cymbalta	C	Unknown	Unk	Not Reported
	Tenormin	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Sumatriptan Succinate	C	Unknown	Unk	Not Reported
	Amitriptyline Hydrochloride	C	Unknown	Unk	Not Reported
	Amitriptyline	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	13188059	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS-2017GMK026159			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Intentional Product Use Issue; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Off Label Use; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Gabapentin			S	Oral	100 Mg, Bid		Glenmark
	Gabapentin			S	Unknown	100 Mg, Bid		Glenmark
	Celebrex			S	Oral	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw (Solution Subcutaneous)		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qw		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Fentanyl Citrate			S	Epidural	Unk		Not Reported
	Fentanyl Matrix			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	1 Df, Qw		Not Reported
	Methotrexate			S	Subcutaneous	1 Df, Qw		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Qw		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	1 Df, Qw		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Qw		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Qw		Not Reported
	Methotrexate			S	Subcutaneous	1 Dosage Form, Qw		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Od		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Od, 1 Every 1 Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Od, 1 Every 1 Day		Not Reported
	Arava			S	Oral	20 Mg, Od		Not Reported
	Arava			S	Unknown	Unk		Not Reported

Leflunomide	S	Oral	20 Mg, Od 1 Every 1 Day	Not Reported
Apo Gabapentin	S	Oral	100 Mg, Bid (2 Every 1 Day)	Not Reported
Apo Gabapentin	S	Unknown	Unk	Not Reported
Apo Celecoxib	S	Oral	Unk	Not Reported
Celecoxib	S	Oral	Unk	Not Reported
Celecoxib	S	Oral	Unk	Not Reported
Nortriptyline Hydrochloride	S	Oral	10 Milligram, 1 Every 1 Hour	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Once Every 3 Weeks (Solution Intramuscular)	Not Reported
Myochrysine	S	Intramuscular	Unk(Solution Intramuscular)	Not Reported
Myochrysine	S	Intramuscular	Unk(Solution Intramuscular); Once Every 3 Weeks	Not Reported
Myochrysine	S	Intramuscular	50 Mg, 1 Every 3 Weeks	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Mg, 1 Every 1 Month	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Mg, 1 Every 1 Month	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Milligram, 1 Every 4 Weeks	Not Reported
Orencia	S	Subcutaneous	Unk, Qw, 1 Every 1 Week	Not Reported
Orencia	S	Subcutaneous	1 Dosage Form, Qw	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Milligram, 1 Every 4 Week	Not Reported
Orencia	S	Vaginal	750 Milligram, 1 Every 1 Month	Not Reported
Oxycontin	S	Unknown	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
Sulfasalazine	S	Oral	2.5 Mg, Od	Not Reported

Sulfasalazine	S	Oral	500 Mg, Qd	Not Reported
Sulfasalazine	S	Oral	2.5 Mg, Od, 1 Every 1 Day	Not Reported
Sulfasalazine	S	Oral	2.5 Gram, Od	Not Reported
Actemra	S	Intravenous (not otherwise specified)	488 Mg, Once Every 1 Month	Not Reported
Actemra	S	Intravenous (not otherwise specified)	468 Mg, Once Every 1 Month	Not Reported
Actemra	S	Intravenous (not otherwise specified)	488 Mg, Once Every 1 Month	Not Reported
Actemra	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Calcium	C	Unknown	Unk	Not Reported
Calcium	C	Unknown	Unk, Od	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Mg, Bid	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg, Od	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	1 Df, Qd	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	400 Iu, Qd	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	Unk, 1 Every 1 Hour	Not Reported
Esomeprazole /01479302/	C	Unknown	40 Mg, Bid	Not Reported
Esomeprazole /01479302/	C	Unknown	400 Mg, Bid	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Mg, Bid	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Mg, Bid	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 International Unit, Od	Not Reported
Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported
Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Mg, Unk	Not Reported
Loperamide	C	Unknown	Unk	Not Reported

Loperamide	C	Unknown	2.5 Milligram	Not Reported
Nasonex	C	Nasal	2 Df, Bid (Spray, Metered Dose)	Not Reported
Nasonex	C	Unknown	2 Df, Bid	Not Reported
Nasonex	C	Nasal	2 Df, Bid	Not Reported
Nortriptyline Hydrochloride W/Perphenazine	C	Oral	10 Mg, Unk	Not Reported
Nortriptyline Hydrochloride W/Perphenazine	C	Oral	Unk, Qd	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Mg, Od	Not Reported
Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	5 Mg, Qd	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	5 Mg, Unk	Not Reported
Trazodone Hydrochloride	C	Oral	50 Mg, Od	Not Reported
Trazodone Hydrochloride	C	Oral	50 Mg, Cyclical	Not Reported
Trazodone Hydrochloride	C	Unknown	Unk	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, 1 Every 1 Hour	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	1 Df, Prn	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	1 Df, Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Once Every 4 Weeks (Intravenous Solution)	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Once Every 1 Month	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported

Aclasta	C	Unknown	Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk (1 Every 2 Weeks)	Not Reported
Actonel	C	Unknown	36 Mg, Qw	Not Reported
Actonel	C	Unknown	Unk	Not Reported
Actonel	C	Unknown	Unk, Od	Not Reported
Tylenol /00020001/	C	Oral	1000 Mg, Od	Not Reported
Tylenol /00020001/	C	Unknown	Unk	Not Reported
Vitamin D /00107901/	C	Unknown	400 Df, Qd	Not Reported
Vitamin D /00107901/	C	Unknown	Unk	Not Reported
Multivitamin /00097801/	C	Unknown	Unk	Not Reported
Omega 3 /01333901/	C	Unknown	1200 Mg, Bid	Not Reported
Omega 3 /01333901/	C	Unknown	Unk	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Tecta	C	Unknown	40 Mg, Qd	Not Reported
Biotin W/Calcium Pantothenate/Colec/06004901/ Docosahexaenoic Acid	C	Unknown	Unk	Not Reported
Aclasta	C	Unknown	1 Df, Qd (1 Every 1 Day)	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, 1 Every 1 Month	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
Docosahexaenoic Acid W/Eicosapentaenoic Acid	C	Unknown	1200 Mg, Bid	Not Reported
Docosahexaenoic Acid W/Eicosapentaenoic Acid	C	Unknown	Unk	Not Reported
Docosahexaenoic Acid W/Eicosapentaenoic Acid	C	Unknown	Unk, Od	Not Reported
Ferrous Fumarate	C	Unknown	Unk	Not Reported

Fish Oil	C	Unknown	1200 Mg, Bid	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Nexium /01479302/	C	Unknown	40 Mg, Bid	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Mg, Cyclical	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Unk, Unk	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Gigabecquerel, 1 Evrey 1 Hour	Not Reported
Pantoprazole	C	Unknown	400 Mg, Od	Not Reported
Pantoprazole	C	Unknown	40 Mg, Od	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Perfenazine	C	Oral	10 Mg, Unk	Not Reported
Perfenazine	C	Unknown	40 Mg, Od, 1 Every 1 Day	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Sodium	C	Unknown	Unk	Not Reported
Sodium Ascorbate	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk, Od, 1 Every 1 Day	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported
Vit D3	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Vitamin A /00056001/	C	Unknown	Unk	Not Reported
Vitamin C /00008001/	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Mg, Od	Not Reported
Fergon	C	Unknown	300 Mg, Od	Not Reported
Nortriptyline	C	Urethral	Unk	Not Reported

Vitamin E /00110501/	C	Unknown	Unk	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Tecta	C	Unknown	Unk	Not Reported
Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
Trazodone	C	Unknown	Unk	Not Reported
Omega-3 /01866101/	C	Unknown	Unk	Not Reported
Nortriptyline Hydrochloride W/Perphenazine	C	Oral	Unk, Qd	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Mg, Unk	Not Reported
Lomotil /00034001/	C	Unknown	Unk	Not Reported
Lomotil /00034001/	C	Unknown	2.5 Milligram, Od	Not Reported
Actonel	C	Unknown	36 Mg, 1 Every 1 Week	Not Reported
Ferrous Gluconate	C	Unknown	Unk	Not Reported
Ferrous Gluconate	C	Unknown	300 Milligram, Od	Not Reported
Trazodone	C	Unknown	Unk	Not Reported
Diphenoxylate	C	Unknown	2.5 Mg, Od	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Genteal /00445101/	C	Unknown	Unk	Not Reported
Genteal /00445101/	C	Ophthalmic	Unk	Not Reported
Oxycodone Hydrochloride W/Oxycodone Terephtha	C	Unknown	1 Df, Unk	Not Reported
Percocet /00867901/	C	Unknown	Unk	Not Reported
Pyridoxine	C	Unknown	Unk	Not Reported
Vitamin B 12	C	Unknown	Unk	Not Reported
Vitamin B12 Aaa	C	Unknown	Unk	Not Reported
Acetaminophen	C	Oral	1000 Mg, Od (1 Every 24 Hours)	Not Reported
Acetaminophen W/Oxycodone	C	Unknown	Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, 1 Every 1 Month	Not Reported
Aclasta	C	Unknown	480 Milligram, 1 Every 1	Not Reported

				Month		
	Lomotil /00034001/	C	Unknown	Unk		Not Reported
	Vitamin B3	C	Unknown	Unk		Not Reported
	Risedronate Sodium	C	Unknown	36 Milligram, 1 Every 1 Week (Qw)		Not Reported
	Diphenoxylate Hydrochloride And Atropine Sulf	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	15208961	EXPEDITED (15-DAY)		HO, OT	GR-ALLERGAN-1835963US			Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Drug Ineffective; Dyspnoea; Leukopenia; Microangiopathic Haemolytic Anaemia; Orthopnoea; Raynaud'S Phenomenon; Renal Impairment; Scleroderma; Scleroderma Renal Crisis; Thrombocytopenia; Weight Decreased	Citalopram Hydrobromide Unk			S	Unknown	Unk		Allergan
	Alprazolam			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Q Week		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisolone			S	Unknown	7.5 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	10 Mg, Qd		Not Reported
	Folate			S	Unknown	5 Mg, Q Week		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Etanercept			S				Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Captopril			S	Unknown	Unk		Not Reported
	Captopril			S				Not Reported
	Valsartan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	15396329	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20180911207		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-	Remicade			S	Intravenous (not			Janssen

Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment			otherwise specified)	
	Simponi	S	Subcutaneous	Janssen
	Simponi	S		Janssen
	Tylenol	S	Unknown	Johnson And Johnson
	Paracetamol	S	Unknown	Johnson And Johnson
	Paracetamol	S	Unknown	Johnson And Johnson
	Arava	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Acetaminophen W/Diphenhydramine Hydrochloride	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported

	Apo-Prednisone	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Acetaminophen W/Codeine Phosphate	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Tylenol W/Codeine No. 3	C	Unknown	Not Reported
	Celebrex	C	Oral	Not Reported
	Hydromorphone Hydrochloride	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Codeine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	15493226	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP022036		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Headache; Joint Swelling; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Tremor; Vitamin D Deficiency	Amlodipine			S	Oral	5 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Asacol			S	Oral	800 Mg, Tid		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, One Every 2		Not Reported

			Weeks	
Methotrexate	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	Unk	Not Reported
Plaquenil /00072602/	S	Oral	Unk	Not Reported
Methotrexate	S	Oral	2.5 Mg, Q.Wk.	Not Reported
Methotrexate	S			Not Reported
Actemra	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Amlodipine Besilate	C	Unknown	Unk	Not Reported
Atacand Plus	C	Unknown	Unk	Not Reported
Bisoprolol Fumarate	C	Unknown	Unk	Not Reported
Depo-Medrol	C	Intra-articular	Unk	Not Reported
Ferrous Gluconate	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Omega Allergenic Extracts	C	Unknown	Unk	Not Reported
Tylenol /00020001/	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	Unk	Not Reported
Zopiclone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	15567436	NON-EXPEDITED			US-PFIZER INC-2018432992		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Clindamycin			S		Unk		Unknown
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	16646824	EXPEDITED (15-DAY)		HO, OT	PL-PFIZER INC-2019317440		35 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis Of Pregnancy; Erythema Nodosum; Maternal Exposure During Pregnancy; Normal Newborn; Ultrasound Scan Abnormal	Sulfasalazine			S	Unknown	Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Encorton			S	Unknown	15 Mg, Qd (Every Day)		Not Reported
	Encorton			S	Unknown	10 Mg, Qd (Every Day)		Not Reported
	Plaquenil S			S		20 Mg, 1x/Day; Qd		Not Reported
	Erelzi [Etanercept]			S	Intravenous (not otherwise specified)	50 Mg, Unk		Not Reported
	Erelzi [Etanercept]			S	Subcutaneous	50 Mg, Qw (Every Week)		Not Reported
	Erelzi [Etanercept]			S	Subcutaneous	50 Mg, Qw (Every Week)		Not Reported
	Benepali			S	Unknown	Unk		Not Reported
	Metex [Methotrexate Sodium]			C	Subcutaneous	Unk (The Last Injection In Jan-2019)		Not Reported
	Insulin			C	Unknown	Unk		Not Reported
	Folic Acid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	16783255	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201805-001712			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Hydroxychloroquine	S	Oral	400 Mg, Qd Tablet	Concordia
	Hydroxychloroquine	S	Unknown	Unk	Concordia
	Erythromycin	S	Unknown	Unk	Not Reported
	Erythromycin	S	Unknown	Unk	Not Reported
	Erythromycin	S	Unknown	Unk	Not Reported
	Erythromycin	S	Unknown	Unk	Not Reported
	Erythromycin	S		Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arthrotec	S	Unknown	Unk	Not Reported
	Arthrotec	S	Intracardiac	Unk	Not Reported
	Bisoprolol Fumarate	S	Unknown	Unk	Not Reported
	Ceclor	S	Unknown	Unk	Not Reported
	Ceclor	S	Unknown	Unk	Not Reported
	Celebrex	S	Oral	200 Mg, Qd	Not Reported
	Demerol	S	Unknown	Unk	Not Reported
	Demerol	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	400 Mg, Unk Subcutaneous Solution	Not Reported
	Humira	S	Subcutaneous	40 Mg; Subcutaneous Solution	Not Reported
	Levofloxacin Hemihydrate	S	Unknown	Unk	Not Reported
	Levofloxacin Hemihydrate	S	Unknown	Unk	Not Reported
	Lyrica	S	Unknown	Unk	Not Reported
	Meperidine Hydrochloride	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	1 Dosage Form, Weekly	Not Reported
	Metronidazole	S	Intravenous (not otherwise specified)	5 Mg	Not Reported

Metronidazole	S			Not Reported
Norfloxacin	S	Unknown	Unk	Not Reported
Norfloxacin	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Cefaclor	S	Unknown	Unk	Not Reported
Pregabalin	S	Unknown	Unk	Not Reported
Lyrica	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Celecoxib	S	Oral	200 Mg	Not Reported
Celecoxib	S	Oral	200 Mg, Qd	Not Reported
Sulfasalazine	S	Unknown	500 Mg	Not Reported
Apo-Bisoprolol	S	Unknown	Unk	Not Reported
Meperidine	S	Unknown	Unk	Not Reported
Levofloxacin	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Erythromycin Estolate	S	Unknown	Unk	Not Reported
Erythro Base	S	Unknown	Unk	Not Reported
Norfloxacin	S	Unknown	400 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	16944449	EXPEDITED (15-DAY)		HO	US-EMCURE PHARMACEUTICALS LTD-2018-EPL-0469		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hypokalaemia; Torsade De Pointes; Ventricular Tachycardia	Ondansetron			S	Intravenous (not otherwise specified)	4 Milligram		Emcure
	Hydroxychloroquine			S		4 Dosage Form		Not Reported
	Activated Charcoal			C	Oral	50 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17182234	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2019-CA-1154329			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anaphylactic Shock; Blood Test Abnormal; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nausea; Renal Impairment; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Otezla			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Doxepin Hydrochloride			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17298077	EXPEDITED (15-DAY)		OT	FR-ACCORD-168315		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acarodermatitis	Mycophenolic Acid			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Cyclophosphamide/Cyclophosphamide Monohydrate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17560623	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567748		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arthralgia; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Headache; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Nausea; Neck Pain; Off Label Use; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Proteinuria; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Treatment Failure; Vasculitis; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Penicillamine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Amitriptyline Hydrochloride			C	Unknown			Not Reported
	Doxycycline			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Tobramycin			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Elavil [Amitriptyline Hydrochloride]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17584892	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2020125649		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bartonella Test Positive; Cat Scratch Disease; Device Dislocation; Pneumonia	Methotrexate Sodium			S		Unk		Pfizer
	Rituximab			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17647567	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200403521			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Rheumatoid Nodule; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17659064	EXPEDITED (15-DAY)		DE, OT	TH-ROCHE-2577353		44 YR	Male	THA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Cerebral Haemorrhage; Injection Site Extravasation; Intentional Product Use Issue; Off Label Use; Proteinuria; Renal Failure	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg/Day		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lopinavir			S	Unknown			Not Reported
	Ritonavir			S	Unknown			Not Reported
	Favipiravir			S	Unknown			Not Reported
	Darunavir			S	Unknown			Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported
	Piperacillin			S	Unknown			Not Reported

	Tazobactam	S	Unknown	Not Reported
	Vancomycin	S	Unknown	Not Reported
	Enoxaparin	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17666251	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009862		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Cyclosporine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S				Apotex
	Apo-Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Neoral			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Neoral			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg, Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Xeljanz Xr			C	Unknown	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17666598	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201712-006550			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blastomycosis; Contraindicated Product Administered; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Knee Arthroplasty; Neoplasm Malignant; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive	Hydroxychloroquine			S	Oral	200 Mg, Bid		Concordia
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Weekly		Not Reported
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported
	Celebrex			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17672025	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200413067		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Elbow Deformity; Headache; Liver Function Test Increased	Simponi			S	Subcutaneous			Janssen
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17672031	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200413062			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Joint Swelling; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Arava			S				Not Reported
	Enbrel			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Plaquenil /00072603/			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17672253	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200411530		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Chloroquine Diphosphate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

	Xeljanz	S	Oral	Not Reported
	Erythromycin	C	Unknown	Not Reported
	Morphine	C	Topical	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17672254	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200411531			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy	Simponi			S	Subcutaneous			Janssen
	Stelara			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Otezla			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17679287	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009833			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cardiac Disorder; Diarrhoea; Drug Ineffective; Dyspepsia; Headache; Hypercholesterolaemia;	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

Impaired Work Ability; Pain; Therapy Non-Responder	Humira	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	716.25 Mg, Unk	Not Reported
	Aspirin /00002701/	C	Unknown	Unk	Not Reported
	Clopidogrel Bisulfate	C	Oral	Unk	Not Reported
	Ezetrol	C	Oral	Unk	Not Reported
	Niaspan Er	C	Unknown	Unk	Not Reported
	Nitroglycerin	C	Transdermal	Unk	Not Reported
	Rosuvastatin Calcium	C	Oral	Unk	Not Reported
	Tylenol /00020001/	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17687090	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003003347			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Failure; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg, Qd (Film-Coated Tablet)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17702991	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226210		53 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Propofol Infusion Syndrome	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Propofol 2% Inyectable Baxter, 1			S	Intravenous (not otherwise specified)	Sedation		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos			S				Not Reported

	Recubiertos, 30 Comprimidos				
	Dexametasona (722a)	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709439	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226654		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hyperbilirubinaemia	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported
	Tocilizumab (8289a)			C	Intravenous (not otherwise specified)	600 Milligram Daily;		Not Reported
	Tocilizumab (8289a)			C				Not Reported
	Azitromicina (7019a)			C	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709444	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202004003560			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Left Ventricular Hypertrophy	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Tofacitinib			C		Unk		Not Reported
	Methotrexate [Methotrexate Sodium]			C		Unk		Not Reported
	Enbrel			C		Unk		Not Reported
	Infliximab			C		Unk		Not Reported
	Orencia			C		Unk		Not Reported
	Rituxan			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709445	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004003658			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pneumonitis; Product Availability Issue	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	200 Mg		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	400 Mg, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709446	EXPEDITED (15-DAY)		OT	BR-ADVANZ PHARMA-202004003877			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rhabdomyolysis	Hydroxychloroquine			S	Oral	600 Mg, Qd		Concordia
	Hydroxychloroquine			S				Concordia
	Tocilizumab			C		200 Mg		Not Reported
	Cholecalciferol			C		3300iu/Mi		Not Reported
	Nitazoxanide			C		500 Mg		Not Reported
	Azithromycin			C		500 Mg		Not Reported
	Bisacodyl			C		5 Mg		Not Reported
	Ceftriaxone			C		1 G		Not Reported
	Enoxaparin Sodium			C		40mg/0.4ml		Not Reported
	Metamizole Sodium			C		1 G		Not Reported
	Midazolam			C		5 Mg		Not Reported
	Etomidate			C		20 Mg		Not Reported
	Esomeprazol			C		40 Mg		Not Reported
	Ondantor			C		8 Mg		Not Reported
	Furosemide			C		20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709452	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245108		48 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia; Overdose	Pantoprazol			S	Intravenous (not otherwise specified)	Unk		Sun
	Tacrolimus Monohydrate			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Pentasa			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709467	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245124		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Azithromycin			S	Oral	500 Milligrams, Daily		Sun
	Plaquenil			S	Oral	600 Milligrams, Daily		Not Reported
	Ceftriaxone Base			C	Unknown	Unk		Not Reported
	Inipomp			C	Unknown	Unk		Not Reported
	Rovamycine			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Xarelto 10 Mg, Comprime Pellicule			C	Oral	Unk		Not Reported
	Diffu K			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709619	EXPEDITED (15-DAY)		LT	FR-TEVA-2020-FR-1226843		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Venlafaxine	S	Oral	225 Mg	Teva
	Loxapine Base	S	Oral	155 Mg	Not Reported
	Plaquenil 200 Mg, Comprimé Pelliculé (Hydroxychloroquine Phosphate)	S	Oral	600 Mg	Not Reported
	Theralene	S	Oral	50 Mg	Not Reported
	Paracetamol	C	Oral	1 Gram	Not Reported
	Nicopatch 7 Mg/24 H, Dispositif Transdermique De 17,5 Mg/10 Cm^2	C	Transdermal	7 Mg	Not Reported
	Diazepam	C	Oral	10 Mg	Not Reported
	Atorvastatine	C	Oral	40 Mg	Not Reported
	Nicotine	C	Oral	12 Mg	Not Reported
	Macrogol 4000	C	Oral		Not Reported
	Nebivolol	C	Oral	7.5 Mg	Not Reported
	Zopiclone	C	Oral	7.5 Mg	Not Reported
	Ramipril	C	Oral	1.25 Mg	Not Reported
	Akineton	C	Oral	4 Mg	Not Reported
	Ezetimibe	C	Oral	10 Mg	Not Reported
	Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet-Dose	C	Oral	75 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709667	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226969		80 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute; Thrombocytopenia	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Enoxaparina (2482a)			S	Subcutaneous	40 Milligram Daily;		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709805	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-032321			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709830	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202004002639			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Treatment Noncompliance	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709947	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226986		63 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hyperbilirubinaemia	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Milligram Daily;		Not Reported
	Amoxicilina / Acido Clavulanico 1 G / 200 Mg Polvo Para Solucion Inyec			S	Intravenous (not otherwise specified)	3 Dosage Forms Daily; Every 8 Hours		Not Reported
	Amoxicilina / Acido Clavulanico 1 G / 200 Mg Polvo Para Solucion Inyec			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710025	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226989		52 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis Cholestatic	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710046	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226987		36 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	4 Dosage Forms Daily; 120 Tablets		Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily; 30 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710093	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-GSH201812-004113			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Transplacental	Unk		Concordia
	Prednisone			S	Transplacental	Unk		Not Reported
	Azathioprine			S	Transplacental	Unk		Not Reported
	Tacrolimus			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710318	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588918		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; No Adverse Event; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710626	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226932		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Leflunomide			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Parenteral			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Tofacitinib			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710627	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226939		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Intestinal Perforation	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710635	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226954		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Infection; Rash; Rheumatoid Arthritis	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Cefazolin			S	Intramuscular			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Arava	C				Not Reported
Naproxen	C	Unknown	1000 Milligram Daily;		Not Reported
Viread	C	Unknown			Not Reported
Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710680	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226998		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Infection; Rash; Rheumatoid Arthritis; Unevaluable Event; Urticaria	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Cefazolin			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Benadryl			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Tofacitinib Citrate			C	Unknown			Not Reported
	Viread			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710682	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226993		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Rash; Rheumatoid Arthritis; Urticaria	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Cefazolin			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Amlodipine			C				Not Reported
	Arava			C				Not Reported
	Benadryl			C	Unknown			Not Reported
	Naproxen			C				Not Reported
	Prednisone			C				Not Reported
	Tofacitinib Citrate			C				Not Reported
	Viread			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710749	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-MYLANLABS-2020M1040162			Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction; No Adverse Event; Oligohydramnios;	Omeprazole			S		Unk		Not Reported
	Calcium Carbonate			S	Transplacental	Unk		Not Reported
	Metoprolol			S	Transplacental	Unk		Not Reported

Premature Baby	Dexamethasone	S	Transplacental	Unk	Mylan
	Dexamethasone	S	Transplacental	Unk	Mylan
	Albumin	S	Transplacental	Unk	Mylan
	Penicillin-G	S	Transplacental	Unk	Mylan
	Prednisone	S	Transplacental	Unk	Mylan
	Prednisone	S	Transplacental	Unk	Mylan
	Vitamin D /00318501/	S	Transplacental	Unk	Mylan
	Hydroxychloroquine	S		Unk	Mylan
	Vitamin B Complex /00003501/	S	Unknown	Unk	Mylan
	Paracetamol	S	Transplacental	Unk	Mylan
	Aminomethylbenzoic Acid	S	Transplacental	Unk	Mylan
	Flebogamma Dif /00025201/	S	Transplacental	Unk	Mylan
	Magnesium Lactate	S	Transplacental	Unk	Mylan
	Bisoprolol Fumarate	S	Transplacental	Unk	Mylan
	Privigen	S	Transplacental	Unk	Mylan
	Privigen	S	Transplacental	Unk	Mylan
	Fluconazole	S	Transplacental	Unk	Mylan
	Hydrocortisone	S	Transplacental	Unk	Mylan
	Vulmizolin	S	Transplacental	Unk	Mylan
	Cefotaxime	S	Transplacental	Unk	Mylan
	Cefotaxime	S	Transplacental	Unk	Mylan
	Potassium Chloride	S	Transplacental	Unk	Mylan
	Folic Acid	S	Transplacental	Unk	Mylan
	Bisulepin	S	Transplacental	Unk	Mylan
	Etamsylate	S	Transplacental	Unk	Mylan
	Nadroparine	S	Transplacental	Unk	Mylan
	Ornidazole	S	Transplacental	Unk	Mylan
	Methylprednisolone	S	Transplacental	Unk	Mylan
	Methylprednisolone	S	Transplacental	Unk	Mylan

	Cefixime	S	Transplacental	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710751	NON-EXPEDITED			US-PFIZER INC-2020165061		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711227	NON-EXPEDITED			US-PFIZER INC-2020167983		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Hypersensitivity; Dyspnoea; Nausea; Swelling; Vomiting; Wheezing	Gabapentin			S		Unk		Pfizer
	Baclofen			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Voltaren [Diclofenac Sodium]			S		Unk		Not Reported
	Escitalopram Oxalate			S		Unk		Not Reported
	Linzess			S		Unk		Not Reported
	Tramadol			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711246	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1227339		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities;	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711270	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226940		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Macule; Skin Cancer	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711308	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1226958		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous	25 Mg, 1 Every 1 Week		Barr
	Indometacin			S	Unknown			Not Reported
	Prednisone			S	Oral	25 Milligram Daily;		Actavis
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported

Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported
	Cymbalta	C	Oral	30 Milligram Daily;	Not Reported
	Folic Acid	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711319	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226935		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous	12 Mg, 1 Every 1 Week		Barr
	Methotrexate			S	Subcutaneous	15 Mg, 1 Every 1 Week		Barr
	Methotrexate			S	Subcutaneous	12.5 Mg, 1 Every 1 Week		Barr
	Methotrexate			S	Unknown	10 Mg, 1 Every 1 Week		Barr
	Methotrexate			S	Subcutaneous	17.5 Mg, 1 Every 1 Week		Barr
	Methotrexate			S	Subcutaneous	10 Mg, 1 Every 1 Week		Barr
	Alendronic Acid			S	Unknown	70 Mg, 1 Every 1 Week		Actavis
	Codeine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported

Orencia	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)	200 Milligram Daily;		Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Ciclosporin	C	Unknown	150 Milligram Daily;		Not Reported
Prednisone	C	Unknown	10 Milligram Daily;		Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711477	EXPEDITED (15-DAY)		OT	NVSC2020FR109492		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis; Drug Eruption; Pyrexia	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Novartis
	Prednisone			C	Unknown	15 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711543	EXPEDITED (15-DAY)		DE, OT	ES-ASTELLAS-2020US014740		21 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hepatitis; Hypocoagulable State; Pancreatitis Acute	Amphotericin B, Liposome			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Astellas
	Hidroxicloroquina [Hydroxychloroquine]			S	Oral			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Not Reported
	Linezolid			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711604	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226653		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mixed Liver Injury	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily; 200 Mg/12h		Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily; 2gr/24h		Not Reported
	Ceftriaxona (501a)			S				Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	4 Dosage Forms Daily; 2 Comp/12h		Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711810	EXPEDITED (15-DAY)		HO, LT	FR-PFIZER INC-2020167297		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree; Bundle Branch Block Left; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711951	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226990		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Infection; Leukopenia; Neutropenia	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr

	Azathioprine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712080	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226652		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily; 500 Mg/24h		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily; 400 Mg/24h		Teva
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600mg Single Dose		Not Reported
	Tocilizumab (8289a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily; 2gr/24h		Not Reported
	Ceftriaxona (501a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712085	EXPEDITED (15-DAY)		LT	FR-TEVA-2020-FR-1226657		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Risperidone			S	Oral	2 Mg		Actavis
	Plaquenil 200 Mg, Comprimé Pelliculé (Hydroxychloroquine Phosphate)			S	Oral	600 Mg		Not Reported
	Effexor L.P. 75 Mg, Gélule À Libération Prolongée			S	Oral	150 Mg		Not Reported
	Acebutolol (Chlorhydrate D')			C	Oral	400 Mg		Not Reported
	Oxazepam			C	Oral	100 Mg		Not Reported
	Enoxaparine Sodique ((Mammifere/Porc/Muqueuse			C	Subcutaneous	4000 Iu		Not Reported

Intestinale))						
Macrogol 4000		C	Oral	2 Df		Not Reported
Amlodipine		C	Oral	10 Mg		Not Reported
Chlorhydrate De Clomipramine		C	Oral	150 Mg		Not Reported
Zopiclone		C	Oral	7.5 Mg		Not Reported
Chlorhydrate De Nicardipine		C	Oral	60 Mg		Not Reported
Hydrochlorothiazide		C	Oral	25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712129	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226773		49 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712237	EXPEDITED (15-DAY)		HO	GR-PFIZER INC-2011075813		56 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia; Urinary Tract Infection; Urinary Tract Pain	Medrol			S	Oral	4 Mg, 1x/Day		Pfizer
	Neoral-Sandimmune (Ciclosporin)			S	Oral	50 Mg, 2x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	200 Mg, 1x/Day		Not Reported
	Thyrohormone			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712238	EXPEDITED (15-DAY)		OT	CA-ROCHE-2587205			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrotic Syndrome	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine Sodium			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712368	EXPEDITED (15-DAY)		OT	NVSC2020CA111106		78 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Retinal Toxicity	Hydroxychloroquine			S	Unknown	5.3 Mg/Kg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	2.7 Mg/Kg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712393	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226967		65 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute; Hyperbilirubinaemia	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712394	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226772		30 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva

	Hidroxicloroquina (2143a)	S				Teva
	Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712720	EXPEDITED (15-DAY)		HO, OT	SE-PFIZER INC-2020167060		16 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Fatigue; Intentional Overdose; Intentional Self-Injury; Somnolence; Tachycardia	Prednisolone			S	Oral	10-15 Df		Pfizer
	Sertraline Hcl			S	Oral	750 Mg		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	10-15 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17713099	DIRECT	Y	LT, OT			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17713314	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200428290		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity;	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17714446	EXPEDITED (15-DAY)		OT	NVSC2020CA111134		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Hydroxychloroquine			S	Unknown	7.1 Mg/Kg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17715382	EXPEDITED (15-DAY)		HO	NVSC2020FR109498		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis; Product Use In Unapproved Indication; Pyrexia; Rash Pustular; Skin Plaque	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17715446	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-033914			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Headache;	Orencia			S	Unknown	Unk		Bristol Myers Squibb

Rheumatoid Arthritis; Tremor	Actemra	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Zopiclone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17715582	EXPEDITED (15-DAY)		OT	CA-ASSERTIO THERAPEUTICS, INC.-CA-2020DEP000202		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus;	Diclofenac Potassium			S	Unknown	50 Mg, Unk		Assertio Therapeutics
	Actemra			S	Unknown	Unk		Not Reported
	Apo Prednison			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	400 Mg, Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported

Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	20 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Weekly	Not Reported
	Methotrexate	S	Oral	25 Mg, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Salazopyrine	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Sulfathalidine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17715715	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-020561		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Condition Aggravated; Hepatocellular Injury	Azithromycin			S	Oral	250 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported

	Rocephine	S	Oral	2 Gram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17715746	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2020-020590			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Off Label Use	Azithromycin			S	Unknown	Unk		Aurobindo
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17715772	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-020598			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Antinuclear Antibody Positive; Arthralgia; Arthritis; Blister; Dry Mouth; Headache; Hypersensitivity Vasculitis; Hypoaesthesia; Joint Swelling; Leukopenia; Lip Swelling; Lymphadenopathy; Menorrhagia; Musculoskeletal Stiffness; Myalgia; Nausea; Parotid Gland Enlargement; Peripheral Swelling; Rheumatoid Arthritis; Sjogren'S Syndrome; Systemic Lupus Erythematosus; Vasculitis	Meloxicam			S	Unknown	Unk		Aurobindo
	Arava			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Breo Ellipta			S		Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Colchicine			S	Unknown	Unk		Not Reported
	Dexilant			S	Oral	60 Milligram, Once A Day		Not Reported
	Estrogel			S	Topical	Unk, Once A Day		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Two Times A Day		Not Reported
	Prednisone			S	Unknown	50 Milligram		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Ventolin Hfa			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17715790	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226775		54 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17715834	EXPEDITED (15-DAY)		HO	SE-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245240		16 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Fatigue; Intentional Overdose; Intentional Self-Injury; Somnolence; Tachycardia	Sertraline			S	Oral	750 Milligram, Unk		Sun
	Prednisolone			S	Oral	10-15st.		Not Reported
	Plaquenil			S	Oral	10-15 St.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	12367074	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-034237		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Orencia			S	Unknown	760 Milligram, Qwk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Alendronate Sodium			S	Oral	70 Milligram, Qwk		Not Reported

Decreased; C-Reactive Protein Increased; Condition Aggravated; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Codeine Sulphate	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Milligram, 2 Times/Wk	Not Reported
	Enbrel	S	Unknown	50 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	25 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	25 Milligram, Q2wk	Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Enbrel	S	Unknown	25.0 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine	S	Oral	20 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	12 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	70 Milligram, Qwk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Unknown	360 Milligram, Qmo	Not Reported
	Simponi	S	Unknown	680 Milligram, Qmo	Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	10 Milligram, Q4wk	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported

Methotrexate	S	Subcutaneous	12 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	70 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	12 Milligram, Q4wk	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Q4wk	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, Q4wk	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, Q4wk	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	1000 Milligram, Bid	Not Reported
Rituximab	S	Unknown	1000 Milligram, Qd	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Actemra	S	Intravenous (not otherwise specified)	360 Milligram, Qmo	Not Reported
Actemra	S	Intravenous (not otherwise specified)	680 Milligram, Q4wk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	2.68 Milligram, Q4wk	Not Reported
Myochrysine	S	Parenteral	50 Milligram, Qmo	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Q2wk	Not Reported
Myochrysine	S	Intramuscular	25 Milligram, Qwk	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Qmo	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	500 Milligram	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
Tocilizumab	S	Unknown	380 Milligram	Not Reported

Tocilizumab	S	Unknown	360 Milligram, Qmo		Not Reported
Tocilizumab	S	Unknown	680 Milligram, Q4wk		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
Alendronic Acid	S	Unknown	70 Milligram, Qwk		Not Reported
Etanercept	S	Unknown	25.0 Milligram, Qwk		Not Reported
Etanercept	S	Unknown	50 Milligram, Qwk		Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Naproxen	S	Unknown			Not Reported
Azathioprine	S	Unknown			Not Reported
Adalimumab	S	Subcutaneous	40 Milligram, Qcycle		Not Reported
Celebrex	S	Unknown			Not Reported
Prednisone	C	Unknown	10 Milligram, Qd		Not Reported
Prednisone	C	Unknown	20 Milligram		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Ciclosporin	C	Unknown	150 Milligram 1 Every 24 Days		Not Reported
Ciclosporin	C	Unknown	150 Milligram, Qd		Not Reported
Prednisolone	C	Unknown	10 Milligram, Qd		Not Reported
Humira	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	13969809	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP018054		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased;	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex

Condition Aggravated; Diarrhoea; Disease Recurrence; Drug Hypersensitivity; Drug Ineffective; Hepatic Enzyme Increased; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lower Respiratory Tract Infection; Nausea; Off Label Use; Osteoarthritis; Pneumonia; Pulmonary Fibrosis; Pulmonary Mass; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure	Apo-Leflunomide	S	Endocervical	Unk	Apotex
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	50 Mg, Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	25 Mg, Qd	Not Reported
	Methotrexate	S	Unknown	25 Mg, Q.Wk.	Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Imuran /00001501/	C	Unknown		Not Reported

Gold	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Arthrotec	C	Unknown	50 Mg, Bid	Not Reported
Atorvastatin	C	Unknown	Unk	Not Reported
Atorvastatin Calcium	C	Unknown	Unk	Not Reported
Bisoprolol	C	Unknown	Unk	Not Reported
Digoxin	C	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	20 Mg, Qd	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Furosemid /00032602/	C	Unknown	Unk	Not Reported
Hydrochlorothiazide	C	Unknown	Unk	Not Reported
Hydrochlorothiazide	C			Not Reported
Lyrica	C	Unknown	75 Mg, Qd	Not Reported
Naproxen	C	Unknown	500 Mg, Qd	Not Reported
Nifedipine	C	Unknown	Unk	Not Reported
Palafer	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	10 Mg, Bid	Not Reported
Prednisone	C	Unknown	5 Mg, Qd	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Tocilizumab	C	Unknown	Unk	Not Reported
Toloxin /00017701/	C	Unknown	Unk	Not Reported
Trazodone	C	Unknown	50 Mg, Qd	Not Reported
Valsartan	C	Unknown	Unk	Not Reported
Xarelto	C	Unknown	Unk	Not Reported
Zinc Citrate	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Unknown	200 Mg, Unk	Not Reported
Hydroxychloroquine	C	Unknown	200 Mg, Q.O.Wk.	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	15935909	EXPEDITED (15-DAY)		DE, OT	IT-ACCORD-104696		67 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Drug Interaction; Haemoptysis; International Normalised Ratio Decreased; Labelled Drug-Drug Interaction Medication Error; Platelet Count Decreased; Product Administration Error; Pyrexia	Hydrochlorothiazide			S		Unk		Not Reported
	Lorazepam			S		Unk, Also Received As Concomitant.		Accord
	Montelukast			S		Unk, Also Received As Concomitant.		Not Reported
	Acetylsalicylic Acid			S		Unk, Also Received As Concomitant		Not Reported
	Celecoxib			S		Unk, Also Received As Concomitant.		Not Reported
	Hydroxychloroquine			S		Unk, Also Received As Concomitant.		Not Reported
	Influenza Vaccine			S		Unk		Not Reported
	Warfarin			S		Regimen 1		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	16081389	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013165		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness;	Risedronate Tablet			S	Unknown	35 Milligram, Every Week		Aurobindo
	Risedronate Tablet			S	Oral	35 Milligram, Every Week		Aurobindo
	Actemra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	300 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	1 Dosage Form, Once A Day		Not Reported

Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Leflunomide	S	Oral	20 Milligram, Once A Day	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Once A Day	Not Reported
	Leflunomide	S	Oral	20 Milligram, Once A Day	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, Once A Day	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram	Not Reported
	Plaquenil	S	Oral	300 Milligram, Once A Day	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	35 Milligram, Every Week	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 Gram, Cyclical (1 Every 1 Day)	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk,Once A Day	Not Reported
	Actonel	S	Unknown	35 Milligram, Every Week	Not Reported
	Hydroxychloroquine	S	Unknown	Unk,Once A Day	Not Reported
	Hydroxychloroquine	S	Unknown	20 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram	Not Reported
	Anakinra	S	Subcutaneous	100.0 Milligram	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	C	Oral	5.0 Milligram, Two Times A Day	Not Reported
	Risedronate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	16358401	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-049379		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Product Use Issue; Rash; Therapeutic Product Effect Decreased	Orencia	S	Unknown	Unk	Bristol Myers Squibb
	Arava	S	Unknown	Unk	Not Reported
	Biaxin	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Ciprofloxacin	S	Unknown	Unk	Not Reported
	Clindamycin	S	Unknown	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enalapril	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Hctz	S	Unknown	Unk	Not Reported
	Hydralazine Hydrochloride	S	Unknown	Unk	Not Reported
	Keflex [Cefalexin]	S	Unknown	Unk	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Losartan	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Metoprolol Tartrate	S	Unknown	Unk	Not Reported
	Moxifloxacin Hydrochloride	S	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	S	Unknown	Unk	Not Reported
	Pariet	S	Unknown	Unk	Not Reported
	Penicillin G 2-Amino-4-Methoxy-6-Methylpyrim.	S	Unknown	Unk	Not Reported
	Plaquenil S	S	Unknown	Unk	Not Reported
	Cephalexin Monohydrate	S	Unknown		Not Reported
	Gliclazide	S	Unknown	Unk	Not Reported
	Hydrochlorothiazide	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Isoniazid	S	Unknown		Not Reported

Lopressor	S	Unknown		Not Reported
Losartan Potassium	S	Unknown		Not Reported
Tecta	S	Unknown		Not Reported
Xeljanz	S	Oral	50 Milligram, Bid	Not Reported
Enalapril Maleate	S	Unknown		Not Reported
Penicillin G [Benzylpenicillin Sodium]	S	Unknown	Unk	Not Reported
Cephalexin [Cefalexin]	S	Unknown	Unk	Not Reported
Clindamycin Phosphate	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Subcutaneous	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Subcutaneous	10 Milligram	Not Reported
Venofer	C	Unknown		Not Reported
Esomeprazole	C	Unknown	Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Unknown	Unk	Not Reported
Iron Sucrose	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	8.5 Milligram, Qd	Not Reported
Atenolol	C	Unknown		Not Reported
Colchicine	C	Unknown		Not Reported
Coversyl [Perindopril Erbumine]	C	Unknown		Not Reported
Leucovorin [Folinic Acid]	C	Unknown		Not Reported
Levothyroxine Sodium	C	Unknown		Not Reported
Ranitidine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	16782017	EXPEDITED (15-DAY)		DS, OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2019VAL000468			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Demerol	S	Unknown	Unk	Validus
	Meperidine Hydrochloride	S	Unknown	Unk	Validus
	Pethidine Hydrochloride	S	Unknown	Unk	Validus
	Leflunomide	S	Unknown	Unk	Not Reported
	Plaquenil /00072603/	S	Oral	400 Mg, Qd	Not Reported
	Erythromycin	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Bisoprolol Fumarate	S	Unknown	Tablet	Not Reported
	Methotrexate	S	Oral	1 Df, Qw	Not Reported
	Metronidazole	S	Unknown	Unk	Not Reported
	Norfloxacin	S	Unknown	Unk	Not Reported
	Cefaclor	S	Unknown	Unk	Not Reported
	Erythromycin	S	Unknown	Unk	Not Reported
	Celecoxib	S	Oral	200 Mg, Qd	Not Reported
	Pregabalin	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Erythromycin Estolate	S	Unknown	Unk	Not Reported
	Levofloxacin	S	Unknown	Unk	Not Reported
	Arthrotec	S	Unknown	Unk	Not Reported
	Plaquenil /00072603/	S	Unknown	Unk	Not Reported
	Norfloxacin	S	Unknown	400 Mg, Unk	Not Reported
	Celecoxib	S	Oral	200 Mg, Unk	Not Reported
	Celecoxib	S	Oral	200 Mg, Qd	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Bisoprolol Fumarate	S	Unknown	Unk	Not Reported
	Bisoprolol	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	400 Mg, Unk	Not Reported
	Diclofenac Sodium And Misoprostol	S	Unknown	Unk	Not Reported

Methotrexate Sodium	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk		Not Reported
Levofloxacin Hemihydrate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	16879886	EXPEDITED (15-DAY)		OT	GR-ACCORD-156263		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Exemestane			S	Unknown	Unk		Not Reported
	Ramipril			S	Unknown	Unk		Accord
	Levothyroxine			S	Oral	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Lansoprazole			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Dicoumarol			S	Unknown	Unk		Not Reported
	Levothyroxine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17299448	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527600		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Celecoxib			C	Oral			Not Reported

	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17351623	EXPEDITED (15-DAY)		DS, OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2020VAL000067			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Demerol			S	Unknown	Unk		Validus
	Pethidine Hydrochloride			S	Unknown	Unk		Validus
	Pethidine Hydrochloride			S	Unknown	Unk		Validus
	Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk, Qw		Not Reported
	Metronidazole			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Norfloxacin			S	Unknown	400 Mg, Unk		Not Reported
	Bisoprolol			S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Cefaclor			S	Unknown	Unk		Not Reported
	Celecoxib			S	Oral	200 Mg, Unk		Not Reported
	Celecoxib			S	Oral	200 Mg, Qd		Not Reported
	Celecoxib			S	Oral	200 Mg, Qd		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin Estolate			S	Unknown	Unk		Not Reported

Levofloxacin	S	Unknown	Unk		Not Reported
Pregabalin	S	Unknown	Unk		Not Reported
Norfloxacin	S	Unknown	Unk		Not Reported
Plaquenil /00072603/	S	Oral	400 Mg, Qd		Not Reported
Plaquenil /00072603/	S	Oral	Unk		Not Reported
Arthrotec	S	Unknown	Unk		Not Reported
Levofloxacin Hemihydrate	S	Unknown	Unk		Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	400 Mg, Unk		Not Reported
Methotrexate Sodium	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17426809	EXPEDITED (15-DAY)		OT	CA-ROCHE-2551542			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17475675	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190801306			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Sepsis; Therapeutic Response Decreased; White Blood Cell Count Decreased	Simponi			S	Subcutaneous	365 Days		Janssen
	Simponi			S				Janssen
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sertraline Hydrochloride			S	Unknown			Not Reported
	Plaquenil /00072602/			C				Not Reported
	Amitriptyline			C				Not Reported
	Constella			C				Not Reported
	Reactine /00884302/			C	Oral			Not Reported
	Aerius /01009701/			C				Not Reported
	Zopiclone			C		7.5 Mg 1/2 -1 Tablet		Not Reported
	Zomig			C				Not Reported
	Vitamin C /00008001/			C				Not Reported
	Acyclovir /00587301/			C	Unknown			Not Reported
	Levofloxacin			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17557583	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318935		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Off Label Use;	Simponi			S	Subcutaneous			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17600443	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-SA-2020SA076630		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present; Gastroenteritis Viral; Human Anti-Human Antibody Test; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of	Hydroxychloroquine Sulfate			S	Oral	5 Mg/Kg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	5 Mg Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Naproxen			S	Oral	5 Mg, Qd		Not Reported
	Naproxen			S	Oral	3 Mg Qd		Not Reported
	Naproxen			S	Unknown			Not Reported
	Naproxen			S				Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S	Oral	1.3 Mg, Bid		Not Reported
	Prednisone			S	Oral	1.3 Mg, Bid		Not Reported
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S	Oral	1.3 Mg Bid		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	50 Mg, Bid		Not Reported
	Prednisone			S	Unknown	50 Mg		Not Reported
	Immunoglobulins [Immunoglobulins Nos]			S	Intravenous (not otherwise specified)			Not Reported

Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Product Use Issue; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Immunoglobulins [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)	70 G	Not Reported
	Immunoglobulins [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)	70 G	Not Reported
	Immunoglobulins [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)	70 G	Not Reported
	Sulfasalazine	S	Oral	250 Mg, Qd	Not Reported
	Methotrexate	S	Subcutaneous	Unk Unk, Qw	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Qow	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg/M2, Qow	Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S			Not Reported
	Triamcinolone Acetonide	S	Intra-articular		Sanofi
	Triamcinolone Acetonide	S	Unknown	Unk	Sanofi
	Triamcinolone Acetonide	S	Unknown		Sanofi
	Triamcinolone Acetonide	S	Unknown	Unk	Sanofi
	Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qw	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qow	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Mg, Bid	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Mg	Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Adalimumab	S	Unknown	Unk	Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Qw	Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Qd	Not Reported
	Anakinra	S	Unknown	50 Mg	Not Reported
	Anakinra	S	Subcutaneous	Unk	Not Reported

Anakinra	S	Subcutaneous	50 Mg, Qd	Not Reported
Anakinra	S	Unknown	Unk	Not Reported
Enbrel	S	Subcutaneous	12.5 Mg, Qw	Not Reported
Enbrel	S	Subcutaneous	25 Mg, Qow	Not Reported
Enbrel	S	Subcutaneous	25 Mg	Not Reported
Enbrel	S	Subcutaneous	25 Mg, Qw	Not Reported
Etanercept	S	Subcutaneous	12.5 Mg	Not Reported
Etanercept	S	Subcutaneous	25 Mg, Qow	Not Reported
Humira	S	Unknown		Not Reported
Humira	S			Not Reported
Humira	S	Subcutaneous	Form: Solution	Not Reported
Humira	S			Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk Unk, Q6w	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	3 Mg/Kg	Not Reported
Infliximab	S	Unknown	5 Mg	Not Reported
Infliximab	S	Unknown	3 Mg/Kg, Q6w	Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S		250 Mg, Qm	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Mg, Q2m	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Mg, Qm	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Mg, Qm	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Mg	Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous drip	250 Mg, Qm	Not Reported

	Orencia	S			Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Qow	Not Reported
	Triamcinolone Hexacetonide	S	Other		Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Unk	Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17605318	EXPEDITED (15-DAY)		OT	AU-SA-2020SA072232		34 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Adrenal Haemorrhage; Atrial Septal Defect; Cerebral Infarction; Deep Vein Thrombosis; Myocardial Hypoperfusion; Myocarditis; Pulmonary Embolism; Pulmonary Infarction; Thrombotic Microangiopathy; Transient Ischaemic Attack	Enoxaparin Sodium			S		200 Mg		Sanofi
	Acetylsalicylic Acid			S		100 Mg		Not Reported
	Hydroxychloroquine			S		200 Mg		Sanofi
	Cyclophosphamide Monohydrate			C	Intravenous (not otherwise specified)	1.5 G		Not Reported
	Heparin Sodium			C				Not Reported
	Rituximab			C		1 G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17611349	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20151008546			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Janssen
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Arava	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Cortisone	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Desoximetasone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17664343	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009853			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Contraindicated Product Administered; Drug Intolerance; Headache; Nausea; Treatment Failure; Vomiting	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Infliximab			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Morphine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17678663	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1224966		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	Unit Dose : 200 Mg 400mg Day		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17691116	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2020-ES-1225788		62 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hepatitis; Long Qt Syndrome	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17693985	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200419445			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy; Synovitis	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17694005	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200419292		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Cough; Drug Ineffective; Headache; Rheumatoid Arthritis; Treatment Failure; Viral Infection	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17715963	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-020588			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Discomfort; Loss Of Consciousness; Off Label Use; Ventricular Arrhythmia	Azithromycin			S	Unknown	Unk		Aurobindo
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17715964	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-020558		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Bisoprolol			S	Unknown	1.25 Milligram, Once A Day		Aurobindo
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716067	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010203			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Hepatotoxicity	Leflunomide			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	6 Mg, Qd		Not Reported
	Pregabalin			S	Unknown	150 Mg, Qd		Not Reported
	Trazodone			S	Unknown	25 Mg, Qd		Apotex
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716135	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589484			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Bupropion			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716273	EXPEDITED (15-DAY)		OT	CA-DRREDDYS-USA/CAN/20/0122393			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Intolerance; Haematochezia; Hepatic Enzyme Increased; Joint Swelling; Muscle Spasms; Nausea; Neuropathy Peripheral; Rash; Skin Burning Sensation	Atorvastatin			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S				Not Reported
	Acetaminophen			C	Oral			Not Reported

	Asa Ec	C	Oral	Not Reported
	Folic Acid	C	Oral	Not Reported
	Vitamin D3	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716326	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1227005		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716375	EXPEDITED (15-DAY)		HO	US-CADILA HEALTHCARE LIMITED-US-ZYDUS-049454			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Simplex Hepatitis	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Zydus Pharm
	Prednisone			S	Unknown	5 Milligram, Qd		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Metronidazole			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716389	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1229781		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Jaw; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716579	EXPEDITED (15-DAY)		HO	MX-ADVANZ PHARMA-202004004174			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Disorder	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716653	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588584			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Celebrex	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716681	EXPEDITED (15-DAY)		HO, OT	RO-ACCORD-136273		56 YR	Female	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Nodule	Methotrexate			S				Accord
	Sulfasalazine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Insulin			C		40 Ui		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716778	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1225767		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Drug Interaction; Electrocardiogram Qt Prolonged; Unresponsive To Stimuli; Ventricular Fibrillation	Azithromycin			S	Oral	On Day 1		Not Reported
	Azithromycin			S	Oral	250 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Oral	800 Milligram Daily; On Day 1		Teva
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Teva
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716808	EXPEDITED (15-DAY)		HO	ES-CIPLA LTD.-2020ES03040			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hyponatraemia	Levofloxacin			S	Oral	500 Milligram, Per Day		Cipla

	Dolquine		S	Oral	400 Milligram, Per Day	Not Reported
	Kaletra		S	Oral	2 Dosage Form, Bid (Every 12 Hours; 2u/12 H)	Not Reported
	Kaletra		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716812	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589371			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Feeding Disorder; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varenicline Tartrate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716905	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-033895			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported

Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Etanercept	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milliliter, Qd	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Tofacitinib Citrate	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17717114	NON-EXPEDITED			US-PFIZER INC-2020168411			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

	Humira	S	Unk	Not Reported
	Orencia	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17717266	EXPEDITED (15-DAY)		DE, OT	CA-ROCHE-2588343		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; C-Reactive Protein Decreased; Crohn'S Disease; Death; Drug Ineffective; Drug Intolerance; Feeling Jittery; Joint Swelling; Limb Discomfort; Localised Infection; Malaise; Musculoskeletal Disorder; Nausea; Neck Pain; Night Sweats; Pain; Peripheral Swelling; Purulent Discharge; Pustular Psoriasis; Synovitis; Tachycardia; Treatment Failure; Vomiting	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown	Therapy Duration: 128.0 Days		Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 176.0 Days		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	Therapy Duration:4 Months		Not Reported
	Xeljanz			S	Oral	Therapy Duration:6 Months		Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Calcium			C	Oral			Not Reported
	Celebrex			C	Unknown			Not Reported
	Elavil [Amitriptyline Hydrochloride]			C	Unknown			Not Reported

	Ergocalciferol	C	Oral	Not Reported
	Leucovorin Calcium	C	Oral	Not Reported
	Lorazepam	C	Oral	Not Reported
	Magnesium	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Valtrex	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17717380	EXPEDITED (15-DAY)		DE	NVSC2020FI113463		7 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Product Use In Unapproved Indication; Respiratory Failure	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Etanercept			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17717567	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2020-IN-001291			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ototoxicity; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Ipca
	Prednisolone			C	Unknown	40 Milligram, Qd		Not Reported
	Prednisolone			C	Unknown	5 Milligram, Qd		Not Reported
	Prednisolone			C	Unknown	10 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17718192	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588809		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive	Actemra			S	Subcutaneous			Not Reported

Protein Abnormal; Drug Ineffective; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Folic Acid	C		Not Reported
	Naproxen	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17718400	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1227002			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Epistaxis; Headache; Insomnia; Joint Swelling; Nausea; Rash; Transaminases Increased; Vasculitis	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Azathioprine			S	Oral	200 Milligram Daily;		Not Reported
	Azathioprine			S	Oral	50 Milligram Daily;		Not Reported
	Azathioprine			S	Oral	150 Milligram Daily;		Not Reported
	Mycophenolate Mofetil			S	Oral	2 Gram Daily;		Teva
	Mycophenolate Mofetil			S	Oral	1000 Milligram Daily;		Teva
	Plaquenil			S	Unknown	300 Milligram Daily;		Not Reported
	Imuran			S	Oral	50 Milligram Daily;		Not Reported
	Imuran			S	Oral	150 Milligram Daily;		Not Reported
	Imuran			S	Oral	200 Milligram Daily;		Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Ketoprofen			C				Not Reported
	Prednisone			C				Not Reported
	Prolia Pre-Filled Syringe. Preservative-Free			C	Subcutaneous			Not Reported

	Quetiapine	C	Oral	25 Milligram Daily;	Not Reported
	Rituximab	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17718444	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588638			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17718533	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588767		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Oral			Not Reported

	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Naprosyn [Naproxen]	C			Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17718649	EXPEDITED (15-DAY)		HO, LT	ES-ABBVIE-20K-144-3380621-00		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia; Pancreatitis Acute	Kaletra 200/50			S	Oral			Not Reported
	Metilprednisolona			S	Intravenous (not otherwise specified)			Not Reported
	Azitromicina			S	Oral			Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Dolquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17718878	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588479			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Vomiting	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Meloxicam	C			Not Reported
	Sulfasalazine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17718922	EXPEDITED (15-DAY)		DS	CA-ROCHE-2588501		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis; Contraindicated Product Administered; Gait Disturbance; Multiple System Atrophy	Actemra			S	Intravenous (not otherwise specified)	7.0 Years		Not Reported
	Rituxan			S	Intravenous drip	579.0		Not Reported
	Enbrel			S	Subcutaneous	9 Months		Not Reported
	Humira			S	Subcutaneous	7 Months		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	2 Years		Not Reported
	Xeljanz			S	Intravenous (not otherwise specified)	2 Years		Not Reported
	Xeljanz			S	Unknown	2 Years		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17719461	EXPEDITED (15-DAY)		OT	NVSC2020SE113735		59 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Neurosensory; Dizziness; Ear Discomfort; Nausea; Tinnitus	Methotrexate			S	Unknown	"Nov 2016 Höjdes Mtx Till 8 Tab/V".		Novartis

Methotrexate	S	Unknown	6 Tabletter		Novartis
Methotrexate	S	Unknown	7 Tabletter		Novartis
Methotrexate	S	Unknown	"6 Tab. Methotrexat/V +5 Mg Prednisolon Under Många År".		Novartis
Plaquenil	S	Unknown			Not Reported
Prednisolone	C	Unknown	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17720803	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3378772-00		49 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Off Label Use; Rash; Rash Maculo-Papular	Lopinavir/Ritonavir			S	Oral			Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17720916	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-020972		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram (1 Total)		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17720923	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-020973		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Hepatitis	Azithromycin		S	Oral	500 Milligram, Once A Day	Aurobindo
	Azithromycin		S			Aurobindo
	Metamizol		S	Intravenous (not otherwise specified)	2 Gram, Four Times/Day	Not Reported
	Hydroxychloroquine		S	Oral	400 Milligram, Once A Day	Not Reported
	Paracetamol		S	Intravenous (not otherwise specified)	1 Gram, 3 Times A Day	Not Reported
	Tocilizumab		S	Intravenous (not otherwise specified)	600 Milligram 1 Total	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17720925	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-020974		47 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S				Aurobindo
	Paracetamol			S	Oral	1 Gram, 3 Times A Day		Aurobindo
	Dexketoprofen			S	Intravenous (not otherwise specified)	25 Milligram, 3 Times A Day		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S				Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram, 1 Total		Not Reported
	Tocilizumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17721027	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245414		73 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azithromycin			S	Oral	500 Mg/24h		Sun
	Hidroxicloroquina (2143a)			S	Oral	200 Mg/24h		Not Reported

	Tocilizumab (8289a)	S	Intravenous (not otherwise specified)	600mg/24h	Not Reported
	Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	2gr/24h	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17722744	DIRECT	Y	DE			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Test Positive; Emergency Care	Hydroxychloroquine			S	Oral			Actavis
	Kaletra			S	Oral			Abbvie

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	12489538	EXPEDITED (15-DAY)		OT	CA-009507513-1606CAN007831		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Contraindicated Product Administered; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Remeron			S	Oral	15 Mg		Merck
	Enbrel			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Lyrica			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Dosage Form Not Specified		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Dosage Form Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	12913683	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		43 YR	Female	CAN

BMS-2016-092891

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	25 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Oral	10 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cortisone			S	Oral	Unk, Prn		Not Reported
	Cortisone Acetate			S	Topical	25 Milligram		Not Reported
	Cortisone Acetate			S	Unknown	25 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Cutaneous	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Oral	5 Milligram		Not Reported
	Folic Acid			S	Oral	1 Milligram		Not Reported

Folic Acid	S	Unknown	1 Dosage Form	Not Reported
Folic Acid	S	Unknown	5 Milligram	Not Reported
Folic Acid	S	Unknown	1 Milligram	Not Reported
Folic Acid	S	Unknown	500 Milligram	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Urethral	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Oral	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	5 Milligram	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Paracetamol	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	25 Milligram	Not Reported

Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	10 Milligram	Not Reported
Sulfathalidine	S	Subcutaneous	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Mg, Bid	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	400 Milligram, Qd	Not Reported
Apo Folic	S	Unknown	5 Milligram	Not Reported
Apo Prednison	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	40 Milligram, Qd	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
Methotrexate	S	Unknown	Unk, Qd	Not Reported
Methotrexate	S	Oral	Unk, Qd	Not Reported
Methotrexate	S	Oral	20 Milligram, Qd	Not Reported

Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
Methotrexate	S	Intra-arterial	25 Milligram, Qwk	Not Reported
Cortisone Acetate	S	Oral	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Unknown	1 Gram, Bid	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous	Unk	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine	S	Unknown	10 Milligram	Not Reported
Cortisone	S	Topical	Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Atasol [Paracetamol]	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	13165249	EXPEDITED (15-DAY)		OT	CA-ROCHE-1886155		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Atorvastatin Calcium			C	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Digoxin			C	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Furosemide			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Nifedipine			C				Not Reported
	Palafer			C				Not Reported
	Pantoprazole			C				Not Reported
	Prednisone			C				Not Reported
	Synthroid			C				Not Reported
	Toloxin [Digoxin]			C				Not Reported
	Valsartan			C				Not Reported
	Vitamin D3			C	Unknown			Not Reported

Xarelto	C	Unknown		Not Reported
Xeljanz	C	Oral		Not Reported
Xeljanz	C	Unknown		Not Reported
Zinc Citrate	C			Not Reported
Naproxen	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	13250722	EXPEDITED (15-DAY)		OT	CA-ROCHE-1894453		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown	Cyclical		Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Therapy Duration: 9 Months		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 4 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 4 Years Cyclical		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 2 Years Cyclical		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Cyclosporine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	14471157	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-004461		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	160 Mg, Unk		Not Reported
	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Mobicox			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulphate			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			C	Unknown	Unk		Not Reported
	Depo-Medrol			C	Intra-articular	80 Milligram, Qd		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Pantoprazole Magnesium			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	15096452	EXPEDITED (15-DAY)		CA, DE, DS, OT	PHHY2018DE028935			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular	Ezetimibe			S	Transplacental	Unk		Novartis

Anomaly; Death; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Product Monitoring Error; Truncus Arteriosus Persistent; Ventricular Septal Defect	Ramipril		S	Transplacental	20 Mg, Unk (Maternal Dose)	Not Reported
	Simvastatin		S	Transplacental	Unk	Not Reported
	Metamizole		S	Transplacental	Unk	Not Reported
	Salbutamol		S	Transplacental	Unk	Not Reported
	Tacrolimus		S	Transplacental	Unk	Not Reported
	Rivaroxaban		S	Transplacental	Unk	Not Reported
	Hydroxychloroquine		S	Transplacental	400 Mg, Qd	Not Reported
	Prednisolone		S	Transplacental	Unk	Not Reported
	Pantoprazole		S	Transplacental		Not Reported
	Aliskiren		S	Unknown	Unk	Not Reported
	Acetylsalicylic Acid		S	Transplacental	100 Mg, Qd	Not Reported
	Torem		S	Transplacental	100 Mg, Qd	Not Reported
	Rasilez		S	Transplacental	300mg/D Unk	Not Reported
	Rasilez		S	Transplacental	100 Mg/D Unk	Not Reported
	Enoxaparin		S	Transplacental	Unk	Not Reported
	Nicotine		S	Transplacental	Unk	Not Reported
	Mifegyne		C	Unknown	Unk	Not Reported
	Cytotec		C	Unknown	Unk	Not Reported
	Cyclophosphamide		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	15102944	EXPEDITED (15-DAY)		OT	PHHY2018DE028933		24 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Exposure During Pregnancy; Maternal Exposure During Pregnancy; Premature Delivery; Product Monitoring Error	Ezetimibe			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Novartis
	Aliskiren			S	Unknown	Unk, Unknown Freq. (0-5 Gw)		Not Reported
	Ramipril			S	Unknown	20 Mg, Unk		Not Reported

	Torasemide	S	Unknown	0-14 Gw	Not Reported
	Simvastatin	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
	Metamizole	S	Unknown	Unk	Not Reported
	Salbutamol	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
	Tacrolimus	S	Unknown		Not Reported
	Rivaroxaban	S	Unknown	0-14 Gw	Not Reported
	Rivaroxaban	S	Unknown	Unk, Unknown Freq. (0-5 Gw)	Not Reported
	Hydroxychloroquine	S	Unknown	0-14 Gw	Not Reported
	Prednisolone	S	Unknown	0-14 Gw	Not Reported
	Acetylsalicylic Acid	S	Unknown	0-14 Gw	Not Reported
	Pantoprazole	S	Unknown	0-14 Gw	Not Reported
	Nicotine	S	Unknown		Not Reported
	Enoxaparin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	15416072	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187971		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Cyst; Bone Erosion; Drug Ineffective; Hypertension; Therapeutic Response Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	C	Unknown	Not Reported
	Desoximetasone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	15593099	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2018445495		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Aphthous Ulcer; Blood Cholesterol Increased; Constipation; Diarrhoea; Headache; Oral Candidiasis; Sinusitis	Xeljanz Xr			S		11 Mg, Unk		Pfizer
	Xeljanz Xr			S		11 Mg, Unk		Pfizer
	Xeljanz Xr			S		11 Mg, 1x/Day		Pfizer
	Xeljanz Xr			S		11 Mg, Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		200 Mg, 2x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Cymbalta			C		Unk		Not Reported
	Clonazepam			C		Unk		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	15964988	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-ACCORD-107431			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby;	Ramipril			S	Transplacental	20 Mg Per Day, Exposure Duration: 0-13+6 Weeks		Accord
	Simvastatin			S	Transplacental	From Gestational Week 0-14		Accord
	Tacrolimus			S	Transplacental	From Gestational Week 0-		Accord

Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect				14	
	Ezetimibe	S	Transplacental	Also Received As Suspect, From Gestational Week 0-14	Not Reported
	Pantoprazole	S	Transplacental	40 Mg/D, 0-13.6 Gestational Week	Not Reported
	Salbutamol	S	Transplacental	From Gestational Week 0-14	Not Reported
	Metamizole Sodium	S	Transplacental	From Gestational Week 0-14	Not Reported
	Nicotine	S	Transplacental	From Gestational Week 0-14	Not Reported
	Dalteparin	S	Transplacental	Unk	Not Reported
	Hydroxychloroquine	S	Transplacental	From Gestational Week 0-14	Not Reported
	Aliskiren	S	Transplacental	300 Mg/D, 0-4.6 Gestational Week	Not Reported
	Prednisolone	S	Transplacental	From Gestational Week 0-14	Not Reported
	Acetylsalicylic Acid Sandoz	S	Transplacental		Not Reported
	Rivaroxaban	S	Transplacental		Not Reported
	Torasemide	S	Transplacental	From Gestational Week 0-14	Not Reported
	Novaminsulfon	S	Transplacental	Unk, Trimester: First, Probably Only In Hospital In Week 5	Not Reported
	Xarelto	S	Transplacental	From Gestational Week 0-5	Not Reported
	Clexane	S	Transplacental	200 Mg/D (2x100)	Not Reported
	Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported
	Cytotec	C	Transplacental	Unk, 13.6 Gestational Week	Not Reported

	Mifegyne	C	Transplacental	Unk, 13.6 Gestational Week	Not Reported
	Cyclophosphamide/Cyclophosphamide Monohydrate	C	Transplacental	3000 Mg Cumulative, Preconceptional	Not Reported
	Enoxaparin	C	Transplacental	Unk Unk, Unknown Freq. (0-14 Gw), Also Received As Concomitant.	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	16080946	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013597		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Rosuvastatin Tablet			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Two Times A Day		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	16478155	EXPEDITED (15-DAY)		CA, DE, HO, OT	FR-ACCORD-135124			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Bowing Of Long Bones; Congenital Osteodystrophy; Foetal Exposure During Pregnancy; Foetal Growth Restriction; Low Birth Weight Baby; Patent Ductus Arteriosus; Premature Baby; Premature Separation Of Placenta; Right-To-Left Cardiac Shunt	Esomeprazole/Esomeprazole Magnesium/Esomeprazole Sodium			S	Transplacental			Not Reported
	Plaquenil			S	Transplacental	Strength: 200 Mg, 1 Dosage Form, Once Daily (Qd)		Not Reported
	Diffu K			S	Transplacental	1 Dosage Form, Once Daily (Qd)		Not Reported
	Cortancyl			S	Transplacental	Strength: 5 Mg, 1 Dosage Form, Once Daily (Qd)		Not Reported
	Imurel			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	16710864	EXPEDITED (15-DAY)		DS, OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2019VAL000394			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Demerol			S	Unknown	Unk		Validus
	Plaquenil /00072603/			S	Oral	400 Mg, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Metronidazole			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Levofloxacin			S	Unknown	Unk		Not Reported
	Norfloxacin			S	Unknown	400 Mg, Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported

Cefaclor	S	Unknown	Unk		Not Reported
Celecoxib	S	Oral	200 Mg, Qd		Not Reported
Humira	S	Subcutaneous	400 Mg, Unk		Not Reported
Lyrica	S	Unknown	Unk		Not Reported
Meperidine /00016301/	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	16719064	EXPEDITED (15-DAY)		OT	CA-SA-2019SA217711		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blastomycosis; Contraindicated Product Administered; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Knee Arthroplasty; Neoplasm Malignant; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive	Arava			S	Oral	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Sanofi
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Qw		Not Reported
	Celebrex			C	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	16880699	EXPEDITED (15-DAY)		OT	CA-ROCHE-2415168			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tylenol	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17182156	EXPEDITED (15-DAY)		OT	NVSC2019CA073777			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Liver Injury; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Psoriatic Arthropathy; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Cosentyx			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported

Humira	S	Subcutaneous	Solution	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk (Injection)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Desoximetasone	S	Unknown	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Etanercept	S	Subcutaneous	Unk	Not Reported
Etanercept	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Quetiapine	C	Unknown	Unk	Not Reported
Ramipril	C	Unknown	Unk	Not Reported
Calcium Gluconate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17259008	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516331		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Swelling	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17339418	EXPEDITED (15-DAY)		HO	CA-ROCHE-2530858		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous	Solution Subcutaneous 100 Mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes		Not Reported
	Kineret			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Synovitis; Vomiting	Naproxen	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Triamcinolone Hexacetonide	C	Unknown	Injectable Suspension	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17401839	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542463		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Unknown			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported

	Remicade	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Hydroxychloroquine	S	Subcutaneous		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17560345	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200309909		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Stelara			S	Subcutaneous			Janssen
	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Janssen
	Remicade			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Reactine (Cetirizine Dihydrochloride)			S	Unknown			Johnson And Johnson
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Johnson And Johnson
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral	And Oral		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	Unknown For 5.0 Mg, Through Oral 25.0 Mg,		Not Reported
	Folic Acid			S	Subcutaneous			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous	Unknown For 5.0 Mg,		Not Reported

		Through Oral 25.0 Mg,	
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sarilumab	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Topicort /00370301/	S	Subcutaneous	Not Reported
Topicort /00370301/	S	Topical	Not Reported
Xeljanz	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported

	Diclofenac		C	Unknown	Not Reported
	Salazopyrin		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17583318	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202003001754			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis Infective; Bartonella Test Positive; Cat Scratch Disease; Device Dislocation; Erythema; Inflammation; Pneumonia; Purulence; Pyrexia; Tenderness	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17669289	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010048		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Maternal Exposure During Pregnancy; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Certolizumab Pegol			S	Subcutaneous	400 Mg, (Cyclical)		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Mg, Q.O.Wk.		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Q.O.Wk.		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Q.Wk.		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17678101	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202004002848			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Drug Ineffective; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17682573	EXPEDITED (15-DAY)		DE, LT, OT	FR-ADVANZ PHARMA-202003002315			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Condition Aggravated; Death; Off Label Use; Pulmonary Embolism	Hydroxychloroquine			S	Oral	800 Mg, Qd, Film Coated Tablet		Concordia
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia
	Paracetamol			C		Unk		Not Reported
	Esomeprazole			C		Unk		Not Reported
	Lansoprazole			C		Unk		Not Reported
	Macrogol 3350			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Sufentanil			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported
	Voriconazole			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Cisatracurium			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17705879	EXPEDITED (15-DAY)		HO	CH-ABBVIE-20K-151-3376752-00		70 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use	Kaletra		S	Oral	800/200 Mg	Not Reported
	Kaletra		S	Oral	400/100 Mg	Not Reported
	Plaquenil		S	Oral	Initial Dose	Not Reported
	Plaquenil		S	Oral		Not Reported
	Plaquenil		S	Oral		Not Reported
	Actemra		C	Intravenous drip		Not Reported
	Co-Amoxi		C			Not Reported
	Triatec [Ramipril]		C			Not Reported
	Metfin		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17716184	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3380425-00		58 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase; Hypertransaminasaemia; Off Label Use	Kaletra			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Piperacillina Sodica/Tazobactam Sodico			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721295	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1229703			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Rheumatoid Arthritis	Ciclosporin			S	Unknown			Ivax
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721359	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588833		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Conjunctivitis; Drug Ineffective; Fatigue; Joint Swelling; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Amlodipine Besilate			C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	Hydrochlorothiazide			C	Oral			Not Reported
	Lyrica			C	Oral			Not Reported
	Mavik			C	Oral			Not Reported
	Olopatadine Hydrochloride			C	Ophthalmic			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721370	EXPEDITED (15-DAY)		OT	ES-ADVANZ PHARMA-GSH201807-002384			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Pulmonary Oedema; Congestive Cardiomyopathy	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721385	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589389		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Fatigue	Actemra			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721386	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588807		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721388	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-GSH201907-001665			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Depressed Level Of Consciousness; Diarrhoea; Fatigue; Headache; Lethargy; Malaise; Mental Status Changes; Muscular Weakness; Myalgia; Nausea; Pyrexia; Tachycardia; Unresponsive To Stimuli; West Nile Viral Infection	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Prednisone			S	Unknown	6 Mg, Qd (Part Of A Regimen That Involved Tapering Of The Dose)		Not Reported
	Prednisone			S				Not Reported
	Methylprednisolone			S	Unknown	High Dose		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Glucocorticoids			S	Unknown			Not Reported
	Sulfamethoxazole-Trimethoprim			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721393	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589542			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Therapeutic Product Effect Decreased	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Bacitracin			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Neomycin Sulfate			S	Unknown			Not Reported
	Polymyxin B Sulfate			S	Unknown			Not Reported
	Prednisone			C	Intramuscular			Not Reported

	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721419	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589692			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721425	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-GSH201801-000313			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Sinus Tachycardia; Torsade De Pointes; Toxicity To Various Agents; Ventricular Arrhythmia; Ventricular Extrasystoles; Ventricular Tachycardia	Hydroxychloroquine			S	Oral	4 Dosage Form, Tablet		Concordia
	Ondansetron Hydrochloride			S	Intravenous (not otherwise specified)	4 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721434	EXPEDITED (15-DAY)		HO, OT	IT-ADVANZ PHARMA-GSH201804-001135			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Back Pain; Blood Lactate Dehydrogenase Increased; C-Reactive Protein Increased; Movement Disorder; Mycobacterial Infection; Mycobacterium Avium Complex Infection; Osteomyelitis; Osteomyelitis; Osteomyelitis Bacterial; Pyrexia	Hydroxychloroquine			S	Oral	Unk		Concordia
	Prednisone			S	Oral	50 Mg, Qd, Administered Initially Which Was Later Tapered To 5 Mg/Day		Not Reported
	Prednisone			S	Oral	5 Mg		Not Reported
	Ceftriaxone			C				Not Reported
	Ceftriaxone			C				Not Reported
	Ceftriaxone			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721454	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245365		63 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Sun
	Paracetamol			S	Oral	1 Gr Cada 8 Horas		Ohm Lab
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721456	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245370		47 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Sun
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg Dia		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721521	EXPEDITED (15-DAY)		OT	ES-HETERO-HET2020ES00451		81 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Condition Aggravated	Levofloxacin			S	Oral	500 Mg, Qd		Hetero
	Dolquine			S	Oral	200 Mg, Qd		Not Reported
	Metronidazol /00012501/			S	Oral	Unk		Not Reported
	Amoxicilina + Acido Clavulonico			S	Oral	Unk, Tid (1 Comp/8h)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721556	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589838		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Adverse Drug Reaction; Arthralgia; Arthropathy; Drug Ineffective; Fatigue; Groin Pain; Joint Injury; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Retinal Toxicity; Rheumatoid Arthritis; Sleep Disorder; Swelling	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rabeprazole Sodium			C	Unknown			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721569	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100957			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S		20 Mg, Qw		Not Reported
	Enbrel			S		25 Mg		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Powder For Solution		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous	40 Mg, Solution Subcutaneous		Not Reported
	Actemra			S				Not Reported
	Bupropion			C				Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721604	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589413		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721617	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588791		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Investigation Abnormal; Loss Of Personal Independence In Daily Activities; Sleep Disorder; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721663	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588955			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721692	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589500			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Fatigue; Groin Pain; Joint Noise; Joint Range Of Motion Decreased; Joint Stiffness; Middle Insomnia; Nonspecific Reaction; Pain In Extremity; Peripheral Swelling; Retinal Toxicity	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721693	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588902		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Neutropenia; Platelet Count Decreased; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Advil [Ibuprofen]			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721734	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1227334		73 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Haemorrhage; Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Piperacilina Tazobactam 4/0.5 G Polvo Para Solucion Inyectable Efg, 1			S	Intravenous (not otherwise specified)	C/24 H		Not Reported
	Ertapenem (2881a)			S	Intravenous (not otherwise specified)	1 Gram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721767	EXPEDITED (15-DAY)		HO, LT, OT	NL-ADVANZ PHARMA-MAPI_00011545			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Hydroxychloroquine			S	Oral	Unk, Coated Tablet		Concordia
	Methotrexate			S	Oral	20 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721783	EXPEDITED (15-DAY)		HO	CA-ROCHE-2588811		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Surgery; Synovitis	Actemra			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Leflunomide	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Folic Acid	C		Not Reported
	Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721865	EXPEDITED (15-DAY)		OT	BR-ADVANZ PHARMA-202004004073			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Hydroxychloroquine			S	Unknown	Unk Coated Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721870	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590364			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722005	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034287			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Rheumatoid	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported

Arthritis; Treatment Failure; Vomiting	Hydroxychloroquine Sulfate		S	Unknown	200 Milligram, Qd	Not Reported
	Infliximab		S	Unknown	Unk	Not Reported
	Leflunomide		S	Unknown	20 Milligram, Qd	Not Reported
	Morphine		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722162	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3377866-00		78 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Electrocardiogram Qt Prolonged	Kaletra			S	Oral			Not Reported
	Midazolam			S	Unknown			Not Reported
	Midazolam			S				Not Reported
	Dolquine			S	Oral	A Compressed Breakfast And Dinner		Not Reported
	Propofol			S	Unknown			Not Reported
	Propofol			S				Not Reported
	Omnic Ocas			C				Not Reported
	Manidon Hta			C				Not Reported
	Rilast Turbuhaler			C				Not Reported
	Simvastatina			C				Not Reported
	Kalpress			C				Not Reported
	Cortic			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722246	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-032531			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported

Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Arava	S	Oral	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Fosamax	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Tocilizumab	S	Subcutaneous		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Etanercept	S	Subcutaneous	Unk	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722270	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590161			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722271	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-02		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722333	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1227342		81 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Condition Aggravated	Levofloxacino (2791a)			S	Oral	500 Milligram Daily;		Teva
	Amoxicilina Acido Clavulanico Sala			S	Oral	1 Comp/8h		Teva
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	1 Comp/24h, 200 Mg		Not Reported
	Metronidazol (1966a)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722337	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1227335		50 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatitis Acute	Azitromicina (7019a)	S	Oral	500 Milligram Daily;	Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S	Oral	400 Milligram Daily;	Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S			Not Reported
	Tocilizumab (8289a)	S	Intravenous (not otherwise specified)	600 Mg	Not Reported
	Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	2 Gram Daily;	Not Reported
	Ceftriaxona (501a)	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722485	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1229997		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Infection; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Risedronate Sodium			S	Unknown	35 Mg, 1 Every 1 Week		Teva
	Methotrexate			S	Subcutaneous	175 Mg		Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)	
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Risedronate	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722622	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228475			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Reactine (Cetirizine)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722635	EXPEDITED (15-DAY)		DS, HO, OT	NVSC2020CA110668		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Arthralgia; Arthritis; Arthropathy; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Creatinine Increased; Blood Parathyroid Hormone Decreased; Blood Pressure Systolic Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Decreased Appetite; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Intolerance; Enthesopathy; Erythema; Fatigue; Fear Of Injection; General Physical Health Deterioration; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Insomnia; Joint Injury;	Adalimumab			S	Subcutaneous	Unk		Novartis
	Codeine Phosphate			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Ciclosporin Sandoz			S	Oral	Unk		Not Reported
	Cyclosporine			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Other (Solution For Injection)		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Mg, Other (Solution For Injection)		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Other (Solution For Injection)		Not Reported
	Methotrexate			S	Oral	4 Df, Qw		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Mg, Qw (Solution For Injection)		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported
	Alendronate Sodium			S	Unknown	70 Mg, Other		Not Reported
	Apo Ibuprofen			S	Oral	600 Mg, Other		Not Reported
	Apo-Cyclosporine			S	Unknown	Unk (Oral Solution)		Not Reported
	Apo-Cyclosporine			S	Oral	Unk (Oral Solution)		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apremilast			S	Unknown	Unk		Not Reported

Joint Swelling; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Apremilast	S	Unknown	60 Mg, Bid	Not Reported
	Apremilast	S	Oral	30 Mg, Bid	Not Reported
	Arava	S	Oral	20 Mg, Qd	Not Reported
	Celebrex	S	Oral	200 Mg, Bid	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	25 Mg, Other	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	25 Mg, Biw	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Etanercept	S	Subcutaneous	Unk	Not Reported
	Golimumab	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Ibuprofen	S	Oral	600 Mg, 6qd	Not Reported
	Ibuprofen	S	Oral	600 Mg, Other	Not Reported
	Ibuprofen	S	Oral	600 Mg, Other	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	400 Mg, Other	Not Reported
	Motrin	S	Unknown	6 Df, Qd	Not Reported
	Motrin	S	Oral	600 Mg, Other	Not Reported
	Motrin	S	Oral	600 Mg, Other	Not Reported
	Motrin	S	Oral	600 Mg, Other	Not Reported
	Motrin	S	Oral	600 Mg, Qd	Not Reported
	Motrin	S	Oral	600 Mg, Other	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Otezla	S	Oral	30 Mg, Bid	Not Reported

Otezla	S	Unknown	Unk	Not Reported
Otezla	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituximab	S	Unknown	1000 Mg, Bid	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Sulfamethoxazole	S	Oral	600 Mg, Other	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Other	Not Reported
Sulfasalazine	S	Unknown	Unk (Tablet)	Not Reported
Tocilizumab	S	Unknown	360 Mg, Other	Not Reported
Ustekinumab	S	Subcutaneous	Unk	Not Reported
Acide Folique	C	Unknown	Unk	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Cannabis Sativa	C	Unknown	Unk	Not Reported
Actonel	C	Oral	35 Mg, Qw	Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Febuxostat	C	Unknown	80 Mg, Bid	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Methotrexate Sodium	C	Oral	Unk Unk, Qw	Not Reported
Mogadon	C	Unknown	5 Mg, Other	Not Reported
Naproxen	C	Unknown	500 Mg, Other	Not Reported
Nitrazepam	C	Oral	Unk	Not Reported
Nitrazepam	C	Unknown	5 Mg, Other	Not Reported
Oxycodone	C	Unknown	10 Mg, Other	Not Reported
Oxycodone	C	Unknown	40 Mg, Other	Not Reported

	Oxycodone Hydrochloride	C	Unknown	40 Mg, Other	Not Reported
	Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
	Oxycodone Hydrochloride	C	Unknown	10 Mg, Other	Not Reported
	Oxyneo	C	Unknown	40 Mg, Other	Not Reported
	Oxyneo	C	Unknown	10 Mg, Other	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Uloric	C	Unknown	80 Mg, Bid	Not Reported
	Uloric	C	Oral	80 Mg, Bid	Not Reported
	Uloric	C	Unknown	Unk	Not Reported
	Uloric	C	Oral	80 Mg, Bid	Not Reported
	Uloric	C	Unknown	Unk	Not Reported
	Uloric	C	Oral	80 Mg, Bid	Not Reported
	Vitamin D3	C	Oral	2000 Iu, Other	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722636	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228692			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	Not Reported
	Remicade	S	Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722673	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010329			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Joint Stiffness; Joint Swelling; Pruritus; Psoriasis	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Cimzia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	300 Mg, Qd		Not Reported
	Alendronate Sodium			C	Oral	70 Mg, Unk		Not Reported
	Atenolol			C	Unknown	3 Df, Unk		Not Reported
	Certolizumab Pegol			C	Subcutaneous	Unk		Not Reported
	Chlordiazepoxide W/Clidinium Bromide			C	Oral	Unk		Not Reported
	Esomeprazole Magnesium Trihydrate			C	Oral	40 Mg, Unk		Not Reported
	Hydrochlorothiazide			C	Oral	25 Mg, Qd		Not Reported
	Lorazepam			C	Oral	1 Mg, Qd		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Oral	Unk		Not Reported
	Trimebutine			C	Unknown	1 Df, Q.12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722685	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589505			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Seborrhoeic Dermatitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722853	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589415			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722899	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228686			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy;	Diclofenac Sodium			S	Unknown			Actavis

Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Prednisone	S	Oral	Actavis
	Methotrexate	S	Intra-arterial	Barr
	Methotrexate	S	Unknown	Barr
	Adalimumab	S	Subcutaneous	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S		Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Desoximetasone	S		Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Tocilizumab	S	Subcutaneous		Not Reported
Cetirizine Hydrochloride,Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Cetirizine Hydrochloride,Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722905	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034249		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Orencia			S	Unknown	750 Milligram, Qd		Bristol Myers Squibb
	Cimzia			S	Unknown	200 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	5 Milligram		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Methotrexate			S	Unknown	5 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Prednisone			C	Unknown	50 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17723476	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590185		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Actemra		S	Intravenous (not otherwise specified)	Not Reported
	Anakinra		S	Subcutaneous	Not Reported
	Apo-Leflunomide		S	Oral	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Methotrexate		S	Oral	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17723713	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020165921		48 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil Sulfate			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17724074	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020166830		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax		S	Oral	Unk	Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]		S	Oral	Unk	Not Reported
	Cefotaxime Mylan		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17724350	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010222		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Pulmonary Mass	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	800 Mg, 1 Every 4 Weeks		Not Reported
	Acetylsalicylic Acid			C	Unknown	81 Mg, Unk		Not Reported
	Calcium Carbonate			C	Unknown	Unk		Not Reported
	Cetirizine			C	Unknown	Unk		Not Reported
	Cranberry /01512301/			C	Unknown	Unk		Not Reported
	Olopatadine			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Quinapril Hydrochloride			C	Unknown	Unk		Not Reported
	Sandoz Rabeprazole			C	Unknown	Unk		Not Reported
	Singulair			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17724725	EXPEDITED (15-DAY)		OT	CA-ROCHE-2586330			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Demyelination; Dermatomyositis; Drug Ineffective; Drug Intolerance; Fatigue; Ill-	Mycophenolate Mofetil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Defined Disorder; Mental Disorder; Muscle Injury; Myalgia; Pruritus; Rash	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17725036	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034298		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Fibromyalgia; Lymphoedema; Obesity; Pneumocystis Jirovecii Pneumonia; Pulmonary Embolism	Abatacept			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Calcium + Vit D			C	Unknown			Not Reported
	Hydrocortisone			C	Unknown	2 Every One Days		Not Reported
	Pantoloc [Pantoprazole]			C	Unknown			Not Reported
	Prednisone			C	Unknown	20 Milligram, Qd		Not Reported
	Tylenol Arthritis Pain			C	Unknown	2 Dosage Form, Bid		Not Reported
	Xarelto			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17725448	EXPEDITED (15-DAY)		OT	NVSC2020CA062017		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug	Methotrexate Sodium			S	Unknown	Unk		Novartis
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

Intolerance; Fatigue; Gastrointestinal Disorder; Joint Swelling; Malaise; Musculoskeletal Stiffness; Nausea; Pain; Spinal X-Ray Abnormal; Stress; Swelling; Tender Joint Count; Therapeutic Response Decreased	Sulfasalazine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17725450	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020166847		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, Daily		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, Daily		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Inipomp			C	Unknown	Unk		Not Reported
	Rovamycine [Spiramycin]			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Xarelto			C	Oral	Unk		Not Reported
	Diffu K			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17725452	EXPEDITED (15-DAY)		HO, LT, OT	CH-PFIZER INC-2020169681		57 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Opportunistic Infection; Product Use In Unapproved Indication	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	800 Mg, Single		Not Reported
	Tavanic			S	Oral	500 Mg, 1x/Day		Not Reported
	Advagraf			C	Oral	4 Mg, 1x/Day		Not Reported
	Calcimagon D3			C		Unk		Not Reported

Cefuroxime	C	Intravenous (not otherwise specified)	1.5 G, 3x/Day		Not Reported
Co-Amoxicillin	C	Intravenous (not otherwise specified)	1.2 G, 3x/Day		Not Reported
Flagyl [Metronidazole]	C	Oral	500 Mg, 3x/Day		Not Reported
Folic Acid	C		Unk		Not Reported
Lasix [Furosemide]	C	Intravenous (not otherwise specified)	40 Mg, 1x/Day		Not Reported
Myfortic	C	Oral	720 Mg, 2x/Day		Not Reported
Tazobac	C	Intravenous (not otherwise specified)	2.25 G, 3x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17725640	EXPEDITED (15-DAY)		HO, OT	CA-SHIRE-CA202014192			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use;	Human Normal Immunoglobulin			S	Unknown			Shire
	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	70 Gram		Shire
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, 1x/Week		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, 1x/2wks		Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, 1x/Day:Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, 1x/Week		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5 Milligram/Kilogram, 1x/Day:Qd		Not Reported
	Infliximab			S	Unknown	5 Milligram		Not Reported

Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab		S	Intravenous (not otherwise specified)	3 Milligram, 1x/Week	Not Reported
	Methotrexate		S	Subcutaneous	Unk Unk, 1x/Week	Not Reported
	Naproxen		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)	250 Milligram, 1x A Month	Not Reported
	Prednisone		S	Oral	10 Milligram, 1x/Day:Qd	Not Reported
	Prednisone		S	Oral	3 Milligram	Not Reported
	Sulfasalazine		S	Oral	250 Milligram, 1x/Day:Qd	Not Reported
	Triamcinolone		S	Unknown		Not Reported
	Triamcinolone Hexacetonide		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17725765	EXPEDITED (15-DAY)		DE, OT	CH-JNJFOC-20200432974		72 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Haemolytic Anaemia; Thrombocytopenia; Thrombotic Microangiopathy	Durogesic Matrix			S	Transdermal	Patch 25 Mcg/H : 1 Tous Les 3 Jours		Janssen
	Plaquenil /00072602/			S	Oral	800 Mg/Jour Du 22 Au 23.03.2020, 400 Mg/Jour Du 24 Au 26.03.2020, 600 Mg/Jour Du 26 Au 30.03.2020		Not Reported
	Doxycycline			S	Oral			Not Reported
	Azithromycine			S	Oral			Not Reported
	Amoxicillin And Clavulanate Potassium			S	Intravenous drip			Not Reported
	Enoxaparin			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17725781	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020166844		56 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bradycardia; Incorrect Product Administration Duration; Off Label Use; Product Use In Unapproved Indication	Zithromax		S	Oral	250 Mg, 1x/Day	Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	600 Mg, 1x/Day	Not Reported
	Cefotaxime Mylan		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17725844	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034644		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Oral	5.0 Milligram, Bid		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Supeudol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17725977	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588805		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17726004	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589054			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Pseudoephedrine Hcl			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17726026	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589868		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17726302	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-020922		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Off Label Use; Pulmonary Fibrosis; Rheumatoid Factor Positive; Synovitis	Risedronate			S	Unknown	35 Milligram, Every Week		Aurobindo
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram Per Kilogram		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Every Hour		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Arava			S	Oral	20 Milligram, Once A Day		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Every Week		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Once A Day		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

			otherwise specified)			
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Xeljanz	S	Oral	5 Milligram, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17726305	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-020924		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Risedronate			S	Unknown	5 Milligram		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Once A Day		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Every Week		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	500 Milligram		Not Reported
	Cyclobenzaprine			C	Unknown	10 Milligram		Not Reported
	Desoximetasone			C	Unknown	5 Milligram		Not Reported
	Desoximetasone			C	Unknown	5 Milligram, Once A Day		Not Reported

Leflunomide	C	Unknown	Unk		Not Reported
Prednisone Acetate	C	Unknown	5 Milligram, Once A Day		Not Reported
Tylenol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17727439	DIRECT	Y	DE			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Cardiac Arrest; Cardiogenic Shock; Renal Failure	Hydroxychloroquine (Hydroxychloroquine So4 200mg Tab)			S	Oral			Not Reported
	Azithromycin (Azithromycin 500mg/Vil Inj)			S	Intravenous (not otherwise specified)	Other Strength:500 Mg/Vil;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	12788076	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-077476		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Arthralgia; Arthropathy; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Creatinine Increased; Blood Parathyroid Hormone Decreased; Blood Pressure Systolic Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Decreased Appetite; Diarrhoea; Drug	Abatacept			S	Subcutaneous	Unk		Bristol Myers Squibb
	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	25 Milligram,2 Every One Week		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported

Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Fatigue; Fear Of Injection; General Physical Health Deterioration; Granuloma Skin; Headache; Hepatic Enzyme Increased; Hypercalcaemia; Hypersensitivity; Infection; Inflammation; Infusion Related Reaction; Insomnia; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Infliximab	S	Intravenous (not otherwise specified)	400 Milligram	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
	Ustekinumab	S	Subcutaneous		Not Reported
	Apremilast	S	Unknown	60 Milligram, Bid	Not Reported
	Apremilast	S	Oral	30 Milligram, Bid	Not Reported
	Ibuprofen	S	Oral	600 Milligram, Q4h	Not Reported
	Golimumab	S	Subcutaneous		Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Ciclosporin	S	Oral	0.6 Milligram	Not Reported
	Ciclosporin	S	Oral	Unk	Not Reported
	Apo-Cyclosporine	S	Oral		Not Reported
	Apo-Cyclosporine	S	Unknown	Unk	Not Reported
	Apo-Ibuprofen	S	Oral	600 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Otezla	S	Oral	30 Milligram, Bid	Not Reported
	Otezla	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Motrin [Ibuprofen]	S	Oral	600 Milligram, Qd	Not Reported
	Motrin [Ibuprofen]	S	Oral	6 Dosage Form, Qd	Not Reported
	Sulfamethoxazole	S	Oral	600 Milligram	Not Reported
	Alendronate Sodium	S	Unknown	70 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not	1000 Milligram, Bid	Not Reported

		otherwise specified)		
Codeine	S	Unknown		Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Methotrexate Sodium	S	Unknown	2.5 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Oral	4 Dosage Form, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Subcutaneous	15 Milligram	Not Reported
Methotrexate Sodium	S	Subcutaneous	17.5 Unk	Not Reported
Methotrexate Sodium	S	Subcutaneous	12.5 Milligram, 1 Every 1 Week	Not Reported
Arava	S	Oral	20 Milligram, 1 Every 1 Days	Not Reported
Celebrex	S	Oral	2000 Milligram, 2 Every 1 Days	Not Reported
Cosentyx	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	1000 Milligram, 2 Every 1 Day	Not Reported
Oxyneo	C	Oral	10 Milligram	Not Reported
Oxyneo	C	Oral	40 Milligram	Not Reported
Mogadon	C	Unknown	5 Milligram	Not Reported
Uloric	C	Unknown	80 Milligram, Bid	Not Reported
Uloric	C	Unknown	Unk	Not Reported
Colchicine	C	Oral	0.6 Milligram	Not Reported
Nitrazepam	C	Oral	5 Milligram	Not Reported
Nitrazepam	C	Oral	Unk	Not Reported
Oxycodone	C	Unknown	10 Milligram	Not Reported
Oxycodone	C	Unknown	40 Milligram	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Febuxostat	C	Unknown	80 Milligram, Bid	Not Reported

	Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk	Not Reported
	Dexilant	C	Unknown	Unk	Not Reported
	Gravol	C	Unknown	Unk	Not Reported
	Oxycodone Hydrochloride	C	Unknown	40 Milligram	Not Reported
	Oxycodone Hydrochloride	C	Unknown	10 Milligram	Not Reported
	Acide Folique	C	Unknown	Unk	Not Reported
	Motrin Children	S	Unknown	Unk	Not Reported
	Prednisone	C	Unknown		Not Reported
	Methotrexate	C	Oral	Unk, 1 Every 1 Week	Not Reported
	Actonel	C	Oral	35 Milligram, Qwk	Not Reported
	Cannabis Sativa	C	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	500 Milligram	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Vitamin D 3	C	Oral	2000 International Unit	Not Reported
	Vitamin D 3	C	Oral	2000 International Unit	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	12887733	EXPEDITED (15-DAY)		OT	CA-ROCHE-1696504		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthritis; Chest Pain; Condition Aggravated; Fine Motor Skill Dysfunction; Gait Disturbance; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Ketorolac			C				Not Reported
	Naproxen			C				Not Reported

	Arthrotec	C			Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	13058759	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015760		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Azathioprine			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, B.I.Wk.		Not Reported
	Gold			S	Intramuscular			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	13976362	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018043		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	25 Mg, Q.Wk.		Apotex
	Apo-Leflunomide			S	Unknown	25 Mg, Q.Wk.		Apotex
	Actemra			S	Unknown	Unk		Not Reported

Arava	S	Unknown	25 Mg, Q.Wk.		Not Reported
Enbrel	S	Unknown	50 Mg, Q.Wk.		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Methotrexate	S	Oral	25 Mg, Q.Wk.		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	14128229	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP020204		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg, Qd		Not Reported
	Methotrexate			C	Subcutaneous	17.5 Mg, Unk		Not Reported
	Methotrexate			C	Subcutaneous	15 Mg, Unk		Not Reported
	Methotrexate			C	Subcutaneous	15 Mg, Q.Wk.		Not Reported
	Sulfasalazine			C	Oral	1 G, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	14633220	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-003769		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain;	Orencia			S	Unknown	Unk		Bristol Myers Squibb

Condition Aggravated; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	20 Milligram, Qd	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Humira	S	Subcutaneous	20 Mg, Qd	Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	20 Milligram 4 Every 1 Week	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	200 Milligram, Bid	Not Reported
	Winpred	S	Oral	5 Milligram, Qd	Not Reported
	Sulfasalazine	S	Unknown	1000 Milligram, Bid	Not Reported
	Apo-Prednisone	S	Oral	5 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	200 Unk	Not Reported
	Prednisone	S	Oral	5 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Etanercept	S	Subcutaneous	50 Milligram	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	14667263	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP007994		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Depression; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Nodule; Off Label Use; Osteoporosis; Pain; Rheumatoid Arthritis;	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	22.5 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

Stress	Celebrex	C	Unknown	200 Mg, Bid		Not Reported
	Plaquenil /00072602/	C	Unknown	Unk		Not Reported
	Vitamin D /00107901/	C	Unknown	4000 Iu, Qd		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported
	Ergocalciferol	C	Unknown	4000 Iu, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	14784955	EXPEDITED (15-DAY)		OT	CA-ROCHE-2108888		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	14917260	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043745			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Drug Ineffective; Glossodynia; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia	S	Intravenous (not otherwise specified)	Unk	Bristol Myers Squibb
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Folic Acid	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Cortisone Acetate	S	Unknown	Unk	Not Reported

	Diclofenac	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	15291706	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015415739		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Stress	Enbrel			S	Subcutaneous	Unk Unk, Weekly		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not	Unk		Not Reported

			otherwise specified)			
	Tylenol	C	Unknown	Unk		Not Reported
	Prednisone	C	Oral	10 Mg, 1x/Day		Not Reported
	Prednisone	C	Oral	6 Mg, 1x/Day		Not Reported
	Mefenamic Acid	C	Unknown	Unk		Not Reported
	Advil	C	Unknown	Unk		Not Reported
	Dequalinium Chloride	C		Unk		Not Reported
	Acetaminophen	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	16177041	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190403869		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Paracetamol			S	Unknown			Johnson And Johnson
	Simponi			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	16323123	EXPEDITED (15-DAY)		OT	AR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-208121		57 YR	Female	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
American	Prednisone			S	Unknown	40 Milligram, Daily		Mutual

Trypanosomiasis; Asthenia; Pyrexia	Hydroxychloroquine	S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17261745	EXPEDITED (15-DAY)		OT	IL-GLAXOSMITHKLINE-IL2019EME238237			Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction	Benlysta			S		Unk		Glaxosmithkline
	Prednisone			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Clexane			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17262610	EXPEDITED (15-DAY)		OT	PHHY2019GR210755		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Ramipril			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Lansoprazole			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Exemestane			S	Unknown	Unk		Not Reported
	Thyroxin			S	Oral	Unk		Not Reported
	Dicumarol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17265311	EXPEDITED (15-DAY)		OT	CA-ROCHE-2262233		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal	Actemra		S	Subcutaneous	Therapy Duration: 5.0 Years	Not Reported
	Enbrel		S	Subcutaneous	Therapy Duration: 11 Years	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown	Therapy Duration: 5.0 Years	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Therapy Duration: 5.0 Years	Not Reported
	Methotrexate		S	Unknown	Therapy Duration: 5.0 Years	Not Reported
	Esomeprazole Magnesium Trihydrate		C	Unknown		Not Reported
	Folic Acid		C	Unknown		Not Reported
	Xeljanz		C	Unknown		Not Reported
	Xeljanz		C	Oral		Not Reported
	Naproxen		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17358352	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532032		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash; Urticaria	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Atenolol	C	Oral	Not Reported
	Hydrochlorothiazide	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17365297	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005932			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not	Unk		Not Reported

				otherwise specified)			
	Hydroxychloroquine		S	Unknown			Not Reported
	Cetirizine Hydrochloride		S	Unknown	Unk		Not Reported
	Diclofenac Sodium		S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17369757	EXPEDITED (15-DAY)		OT	CA-ROCHE-2538294			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17390099	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200153298			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Hypersensitivity; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Simponi	S	Subcutaneous	Janssen
	Simponi	S	Subcutaneous	Janssen
	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Stelara	S	Subcutaneous	Janssen
	Stelara	S	Subcutaneous	Janssen
	Cimzia	S	Subcutaneous	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Otezla	S	Oral	Not Reported
	Otezla	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17423283	NON-EXPEDITED		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-00169		51 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Porphyria Acute	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17433123	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0805			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Ill-Defined Disorder; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Off Label Use	Kineret			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous	Not Specified		Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Solution		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Gold			S				Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			C	Unknown	Not Sepcified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17433133	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0824		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; Arthropathy;	Kineret			S	Unknown			Not Reported

Condition Aggravated; Deformity; Diarrhoea; Disease Progression; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Joint Swelling; Musculoskeletal Disorder; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Warfarin	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Warfarin	S	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17450609	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007837		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Ineffective; Thrombosis	Hydroxychloroquine			S	Unknown	200 Mg, Q.12h		Apotex
	Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Methotrexate			S	Oral	15 Mg, Q.Wk.		Not Reported
	Sulfasalazine			C	Unknown	1000 Mg, Bid		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17557584	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20200318937		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Muscle Spasms; Rheumatoid Arthritis	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Acetaminophen W/Oxycodone Hydrochloride			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Thiamine Hydrochloride			C				Not Reported
	Oxycodone Terephthalate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17656097	EXPEDITED (15-DAY)		LT, OT	FR-SA-2020SA080271		71 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alkalosis; Alkalosis; Atrial Flutter; Deep Vein Thrombosis; Drug Level Increased; Enterococcal Infection; Haematuria; Haemoglobin Decreased; Hyperglycaemia; Hypoxia; Quadriparesis; Staphylococcal Infection; Vascular Device Infection	Hydroxychloroquine Sulfate			S	Other	600 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Other	1000 Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Other	400 Mg, Qd		Sanofi
	Lovenox			S	Subcutaneous	0.6 Ml, Qd		Sanofi
	Lovenox			S				Sanofi
	Paracetamol			S	Other	4 G, Qd		Not Reported
	Paracetamol			S				Not Reported
	Movicol [Macrogol			C	Other	2 Df, Qd		Not Reported

3350;Potassium Chloride;Sodium Bicarbonate;Sodium Ch					
Movicol [Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Ch	C				Not Reported
Dexamethasone	C	Intravenous (not otherwise specified)	20 Mg, Qd		Not Reported
Lasilix [Furosemide]	C	Parenteral	40 Mg, Qd		Not Reported
Lantus	C	Subcutaneous	20 Iu, Qd		Not Reported
Pantoprazole	C	Oral	40 Mg, Qd		Not Reported
Pantoprazole	C				Not Reported
Pantoprazole	C				Not Reported
Tienam	C	Intravenous (not otherwise specified)	1 G, Q8h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17671014	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031107		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Cough; Dyspnoea; Oropharyngeal Pain; Painful Respiration	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Prednisone			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17692947	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202004002601			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Respiratory Failure	Hydroxychloroquine			S		400 Mg, Qd (Film-Coated Tablet)		Concordia
	Ceftriaxone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17702980	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012108			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Metronidazole			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Bausch And Lomb
	Erythromycin			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Demerol			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Norfloxacin			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Meperidine Hydrochloride			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726376	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588721			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Drug Reaction; Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726381	EXPEDITED (15-DAY)		HO, OT	GB-ADVANZ PHARMA-GSH201806-002096			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Altered State Of Consciousness; Decreased Appetite; Headache; Hypoglycaemia	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Concordia
	Hydroxychloroquine			S				Concordia
	Cellcept			C		500 Mg, Bid		Not Reported
	Alfacalcidol			C				Not Reported
	Amlodipine			C				Not Reported
	Pantoprazole			C				Not Reported
	Atenololol			C		50 Mg, Freq: Unk X 1 Days		Not Reported
	Prednisolone			C		10 Mg, Freq: Unk X 1 Days		Not Reported
	Furosemide			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Icodextrin			C				Not Reported
	Dianeal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726434	EXPEDITED (15-DAY)		HO, LT	FR-SUN PHARMACEUTICAL		67 YR	Male	FRA

INDUSTRIES LTD-
2020RR-245618

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Extrasystoles; Ventricular Tachycardia	Azithromycin			S	Oral	500 Mg J1 Puis 250 Mg Par Jour ()		Sun
	Plaquenil			S	Oral	600 Milligrams, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726480	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-E2B_00007901			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Cardiac Arrest; Electrocardiogram Qt Prolonged; Electrocardiogram U Wave Present; Hypokalaemia; Hypomagnesaemia; Hypotension; Intentional Overdose; Overdose; Somnolence; Torsade De Pointes; Ventricular Fibrillation	Hydroxychloroquine			S	Unknown	60 Tablets, 1200 Mg Total Dose		Concordia
	Oxycodone, Paracetamol			S	Unknown	35 Tablets (5/325 Mg)35 Dosage Form Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726496	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590320			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Nodule; Treatment Failure	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

	Simponi		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726545	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589092			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Cetirizine;Pseudoephedrine			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726564	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589944			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Naproxen			C				Not Reported
	Lyrica			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726623	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590207			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Gastrointestinal Toxicity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Lipitor			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726709	EXPEDITED (15-DAY)		DE, OT	FR-ADVANZ PHARMA-202004004067			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Organ Dysfunction Syndrome; Off Label Use; Septic	Hydroxychloroquine			S	Oral	400 Mg, Qd (Film-Coated Tablet)		Concordia

Shock

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726710	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589755			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726929	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202004004141			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Off Label Use	Hydroxychloroquine			S	Oral	200 Mg, Qd Film-Coated Tablet		Concordia

	Hydroxychloroquine	S			Concordia
	Amoxicillin Clavulanic Acid	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726980	EXPEDITED (15-DAY)		OT	NL-ACCORD-071584		60 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Toxicity; Treatment Failure	Methotrexate			S				Accord
	Prednisone			C				Not Reported
	Hydroxychloroquine			S				Not Reported
	Azathioprine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727035	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020168024		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727036	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020167372		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Pr Prolongation; Electrocardiogram T Wave Inversion; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727049	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020017786		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster	Cimzia			S	Subcutaneous	400 Milligram		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram, Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727077	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589398		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Inappropriate Schedule Of Product Administration; Malignant Melanoma; Mobility Decreased; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Restasis			C	Unknown			Not Reported
	Sulfasalazine			C	Oral			Not Reported
	Synthroid			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727131	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589814			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Rheumatoid Arthritis	Actemra		S	Unknown		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		C			Not Reported
	Wellbutrin		C	Unknown	Tablet (Extendedrelease	Not Reported
	Xeljanz		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727217	EXPEDITED (15-DAY)		DE	ES-ABBVIE-20K-144-3384129-00		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Cardio-Respiratory Arrest	Kaletra 200/50			S	Oral			Not Reported
	Kaletra 200/50			S				Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Azitromicina			S	Oral			Not Reported
	Dolquine			S	Oral			Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727313	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-GSH201902-000459			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Muscular Weakness; Neuromyopathy; Weight Decreased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Unknown	200 Mg, Qd		Concordia
	Losartan	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727333	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588915			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727336	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034554			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia	S	Intravenous (not otherwise specified)	Unk	Bristol Myers Squibb
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Topical	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Phthalylsulphathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727348	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034905			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Product Use Issue; Therapeutic Product Effect Decreased; Therapeutic	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	162 Milligram, Qwk		Not Reported
	Apo-Prednisone			S	Unknown	1 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported

Product Effect Incomplete	Azathioprine	S	Oral	200 Milligram, Qd	Not Reported
	Depo-Medrol With Lidocaine	S	Intra-articular		Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram, Qd	Not Reported
	Ketoprofen	S	Topical	Unk, Qid	Not Reported
	Leucovorin Calcium	S	Unknown	1 Dosage Form, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	15 Unk	Not Reported
	Prevnar 13	S	Intramuscular	0.5 Milligram, Total	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727372	EXPEDITED (15-DAY)		HO	FR-SA-2020SA111792		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Off Label Use	Plaquenil			S	Oral	600 Mg, Qd		Sanofi
	Plaquenil			S				Sanofi
	Doliprane			S	Oral	4000 Mg, Qd		Not Reported
	Lovenox			S	Subcutaneous	1 Df, Qd		Sanofi
	Azithromycin			S	Oral	1 Df, Qd		Not Reported
	Kaleorid Lp			C	Oral	3 Df, Qd		Not Reported
	Metformin Almus			C	Oral	Unk		Not Reported
	Gliclazide Arrow			C	Oral			Not Reported
	Atorvastatin Arrow			C	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727386	EXPEDITED (15-DAY)		OT	IT-ACCORD-180018		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Pyrexia; Systemic Lupus Erythematosus; Therapy Non-Responder	Tacrolimus			S				Accord
	Mycophenolic Acid			S				Not Reported
	Hydroxychloroquine			S		400 Mg, Qd		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Prednisone			S		Unk Unk (12.5 Mg Qd, Dose Tapering)		Not Reported
	Methylprednisolone			C		Unk (Pulses)		Not Reported
	Immunoglobulins (Ivig)			C		Unk		Not Reported
	Rituximab			C		Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Prednisone			S		Unk Unk (10 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S		Unk Unk (15 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S		25 Mg, Qd		Not Reported
	Prednisone			S		Unk (50 Mg Qd, Tapering Dose)		Not Reported
	Prednisone			S		Unk Unk (7.5 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S		Unk (25 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S		15 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728025	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-033863			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia;	Orencia			S	Intravenous (not	Unk		Bristol Myers Squibb

Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus			otherwise specified)			
	Actemra	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk		Not Reported
	Cimzia	S	Subcutaneous	Unk		Not Reported
	Diclofenac Sodium	S	Unknown	Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Folic Acid	S	Unknown	Unk		Not Reported
	Fosamax	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728040	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034901			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

Methotrexate	S	Subcutaneous	Unk		Not Reported
Methotrexate	S	Oral	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 Gram		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Tocilizumab	S	Unknown	Unk		Not Reported
Tofacitinib	S	Unknown	Unk		Not Reported
Xeljanz	S	Unknown	Unk		Not Reported
Rabeprazole Sodium	C	Oral	20 Milligram, Every 14 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728203	EXPEDITED (15-DAY)		HO	MX-TEVA-2020-MX-1231149		29 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Abscess; Endophthalmitis; Liver Abscess; Muscle Abscess; Nocardiosis; Perinephric Abscess; Pyomyositis	Mycophenolate Mofetil			S	Oral	2.5 Gram Daily; Scheduled For 2 Months		Teva
	Prednisone			S	Oral	30 Milligram Daily; Scheduled For 2 Months		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram Daily; Scheduled For 2 Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728379	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2020AMR072153			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Burning Sensation; Muscle Spasms	Benlysta			S	Unknown	Unk		Glaxosmithkline
	Plaquenil (Hydroxychloroquine)			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728437	EXPEDITED (15-DAY)		CA	DE-TEVA-2020-DE-1228290			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Talipes	Prednisolone			S	Transplacental			Actavis
	Hydroxychloroquine			S	Transplacental			Teva
	Certolizumab			S	Transplacental			Not Reported
	Sulfasalazine			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728554	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228769			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Exposure During Pregnancy; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)			
	Simponi	S	Subcutaneous	Powder For Solution For Pre-Filled Syringe		Not Reported
	Tocilizumab	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728562	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228718			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazol			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728575	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228801			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Alendronate Sodium			S	Unknown			Actavis
	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Intra-arterial	25 Milligram Daily;		Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Phosphate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

	Sulfasalazine		S	Unknown	Not Reported
	Xeljanz		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728607	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1228759		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Live Birth; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Acetaminophen			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Actavis
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo Prednison			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone			S	Oral			Not Reported
	Cortisone Acetate			S	Oral			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported

Desoximetasone	S	Unknown		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Folic Acid	S	Unknown		Not Reported
Folic Acid	S	Unknown		Not Reported
Folic Acid	S	Oral		Not Reported
Folic Acid	S	Oral		Not Reported
Fosamax	S	Oral		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Oral	400 Milligram Daily;	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral	40 Milligram Daily;	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram Daily;	Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral	20 Milligram Daily;	Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Intra-arterial	25 Milligram Daily;	Not Reported
Methotrexate	S	Oral	25 Milligram Daily;	Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Methotrexate Sodium	S	Subcutaneous		Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Phthalylsulfathiazole	S	Subcutaneous		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported

Plaquenil	S	Oral	40 Milligram Daily;	Not Reported
Plaquenil	S	Unknown	40 Milligram Daily;	Not Reported
Plaquenil	S	Unknown		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
Remicade	S	Endocervical		Not Reported
Remicade	S			Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Sarilumab	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Intravenous (not otherwise specified)		Not Reported
Stelara	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral	1 Gram Daily;	Not Reported
Topicort	S	Oral		Not Reported
Topicort	S	Oral		Not Reported
Topicort	S	Subcutaneous		Not Reported
Xeljanz	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Salazopyrin	C	Unknown		Not Reported
Tofacitinib Citrate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728614	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034852		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Drug Ineffective; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Orencia	S	Intravenous (not otherwise specified)	Unk	Bristol Myers Squibb
	Orencia	S	Unknown	Unk	Bristol Myers Squibb
	Actemra	S	Unknown	Unk	Not Reported
	Apo Prednison	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	400 Milligram	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Cortisone Acetate	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Diclofenac	S	Unknown	50 Milligram	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	400 Milligram, Qd	Not Reported
	Prednisone	S	Unknown		Not Reported
	Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Salazopyrine	S	Unknown		Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral		Not Reported

Sulfathalidine	S	Unknown			Not Reported
Xeljanz	S	Unknown			Not Reported
Methotrexate	S	Oral	25 Milligram		Not Reported
Methotrexate	S	Unknown	20 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729022	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020141193		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Condition Aggravated; Drug Ineffective; Gait Disturbance; Hypoaesthesia; Joint Swelling; Muscular Weakness; Nerve Injury; Off Label Use; Pain; Product Use Issue; Sciatica; Spinal Stenosis	Methotrexate Sodium			S				Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	2 G, Q Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, 2x/Day		Pfizer
	Plaquenil			S	Unknown	400 Mg, Q Unk		Not Reported
	Plaquenil			S		400 Mg, 1x/Day		Not Reported
	Actonel Xr			C	Unknown	75 Mg Q Unk		Not Reported
	Baclofen			C	Unknown	10 Mg, Daily At Night (Qhs)		Not Reported
	Folic Acid			C	Unknown	5 Mg, 1x/Day		Not Reported
	Lyrica			C	Unknown	75 Mg, 1x/Day		Not Reported
	Prednisone			C	Oral	7.5 Mg, 1x/Day		Not Reported
	Vitamin D			C	Unknown	2000 Iu, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729036	NON-EXPEDITED			GR-LUPIN PHARMACEUTICALS INC.-2020-00627		40 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729108	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020017788		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Mass; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	200 Milligram, Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Gold			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729119	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228814			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown			Actavis
	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported

Cortisone Aceta	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil[Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729176	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228816		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Maternal Exposure During Pregnancy;	Diclofenac			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Unknown			Actavis
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Apo Prednison			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled			S	Unknown			Not Reported

Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Syringe				
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Unknown	400 Milligram Daily;	Not Reported
	Rituxan	S	Unknown		Not Reported
	Salazopyrine	S	Unknown		Not Reported
	Sulfathalidine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729197	EXPEDITED (15-DAY)		DE	ES-FRESENIUS KABI-FK202004240		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Electrocardiogram Qt Prolonged; Sudden Death	Propofol (Manufacturer Unknown)	S	Intravenous (not otherwise specified)	Not Reported
	Salbutamol	S	Respiratory (inhalation)	Not Reported
	Azithromycin	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Metoclopramide Hydrochloride	S	Intravenous (not otherwise specified)	Not Reported
	Ipratropium Bromide	C	Respiratory (inhalation)	Not Reported
	Enoxaparin Sodium	C	Subcutaneous	Not Reported
	Cefotaxime	C	Intravenous drip	Not Reported
	Midazolam	C	Intravenous drip	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729226	EXPEDITED (15-DAY)		HO	NVSC2020IN115852		29 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Bullous; Dysphagia; Mouth Ulceration; Ocular Hyperaemia; Product Use In Unapproved Indication; Skin Exfoliation; Toxic Epidermal Necrolysis	Hydroxychloroquine			S	Unknown	100 Mg, Bid		Novartis
	Mycophenolate Mofetil			C	Unknown	1.5 G, Bid		Not Reported
	Prednisolone			C	Unknown	30 Mg, Qd		Not Reported
	Prednisolone			C	Unknown	60 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729374	EXPEDITED (15-DAY)		OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2020VAL000340			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International	Demerol			S	Unknown	Unk		Validus
	Meperidine Hydrochloride			S	Unknown	Unk		Validus

Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate	S	Oral	400 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Bisoprolol	S	Unknown	Unk	Not Reported
	Cefaclor	S	Unknown	Unk	Not Reported
	Celecoxib	S	Oral	200 Mg, Qd (1 Df, Every 1 Day)	Not Reported
	Erythromycin	S	Unknown	Unk	Not Reported
	Erythromycin	S	Unknown	Unk	Not Reported
	Levofloxacin	S	Unknown	Unk	Not Reported
	Pregabalin	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Metronidazole	S	Unknown	Unk	Not Reported
	Norfloxacin	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Arthrotec	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	400 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729461	EXPEDITED (15-DAY)		OT	NVSC2020IN115930		51 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Neurosensory; Product Use In Unapproved Indication; Tinnitus	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Novartis
	Prednisolone			C	Unknown	40 Mg, Qd (Gradual Taper To 5 Mg/Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729486	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228819			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Exposure During Pregnancy; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729492	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228815			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort; Antinuclear Antibody Positive; Arthralgia;	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Barr

Arthritis; Blister; Dry Mouth; Headache; Hypersensitivity Vasculitis; Hypoaesthesia; Joint Swelling; Leukopenia; Lip Swelling; Lymphadenopathy; Menorrhagia; Musculoskeletal Stiffness; Myalgia; Nausea; Parotid Gland Enlargement; Peripheral Swelling; Rheumatoid Arthritis; Sjogren'S Syndrome; Systemic Lupus Erythematosus; Vasculitis	Prednisone	S	Unknown		Actavis
	Celebrex	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Belimumab	S	Unknown		Not Reported
	Breo Ellipta	S	Respiratory (inhalation)		Not Reported
	Colchicine	S	Unknown		Not Reported
	Dexilant	S	Oral	60 Milligram Daily;	Not Reported
	Estrogel	S	Topical		Not Reported
	Methotrexate	S	Oral		Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ventolin Hfa	S	Respiratory (inhalation)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729669	EXPEDITED (15-DAY)		DE	ES-PFIZER INC-2020171686		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Off Label Use; Product Use In Unapproved Indication; Tachyarrhythmia	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 1x/Day		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Ceftriaxon			C	Intravenous (not otherwise specified)	1 G, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729799	EXPEDITED (15-DAY)		LT	FR-PFIZER INC-2020171243		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Venlafaxine Hcl		S	Oral	225 Mg, 1x/Day	Pfizer
	Loxapine		S	Oral	155 Mg, 1x/Day	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	600 Mg, 1x/Day	Not Reported
	Theralene		S	Oral	50 Mg, 1x/Day	Not Reported
	Paracetamol		C	Oral	1 G, 1x/Day	Not Reported
	Akineton [Biperiden Hydrochloride]		C	Oral	4 Mg	Not Reported
	Macrogol 4000		C	Oral	Unk	Not Reported
	Atorvastatin		C	Oral	40 Mg, 1x/Day	Not Reported
	Ezetimibe		C	Oral	10 Mg, 1x/Day	Not Reported
	Kardegic		C	Oral	75 Mg, 1x/Day	Not Reported
	Nebivolol		C	Oral	7.5 Mg, 1x/Day	Not Reported
	Ramipril		C	Oral	1.25 Mg, 1x/Day	Not Reported
	Diazepam		C	Oral	10 Mg, 1x/Day	Not Reported
	Nicopatch		C	Transdermal	7 Mg, 1x/Day	Not Reported
	Nicotine		C	Oral	12 Mg, 1x/Day	Not Reported
	Zopiclone		C	Oral	7.5 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729886	EXPEDITED (15-DAY)		LT	FR-PFIZER INC-2020171246		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Effexor Lp			S	Oral	150 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported
	Risperidone			S	Oral	2 Mg, 1x/Day		Not Reported
	Acebutolol Hydrochloride			C	Oral	400 Mg, 1x/Day		Not Reported
	Oxazepam			C	Oral	100 Mg, 1x/Day		Not Reported
	Sodium Enoxaparin			C	Subcutaneous	4000 Iu, 1x/Day		Not Reported
	Macrogol 4000			C	Oral	2 Df, 1x/Day		Not Reported

Amlodipine	C	Oral	10 Mg, 1x/Day		Not Reported
Clomipramine Hydrochloride	C	Oral	150 Mg, Monthly		Not Reported
Zopiclone	C	Oral	7.5 Mg, 1x/Day		Not Reported
Nicardipine Hydrochloride	C	Oral	60 Mg, 1x/Day		Not Reported
Hydrochlorothiazide	C	Oral	25 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729999	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020017804		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product Administration; Liver Function Test Increased; Rash; Rheumatoid Arthritis; Treatment Failure	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram,Solution		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S				Not Reported
	Orencia			S		125 Milligram, Weekly (Qw)		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Simponi			C	Subcutaneous	50 Milligram, Monthly (Qm)		Not Reported
	Sulfasalazine			C				Not Reported
	Prednisone			C				Not Reported
	Leflunomide			C				Not Reported
	Xeljanz			C	Oral	5mg 2every 1day		Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17730004	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228746			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Acetaminophen	S	Unknown	Not Reported
	Diclofenac Sodium	S	Unknown	Actavis
	Leflunomide	S	Unknown	Barr
	Methotrexate	S	Unknown	Barr
	Methotrexate	S		Barr
	Prednisone	S	Unknown	Actavis
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Oral	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Desoximetasone	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Oral	Not Reported
	Fosamax	S	Oral	Not Reported
	Fosamax	S	Unknown	Not Reported
	Golimumab	S	Unknown	Not Reported
	Golimumab	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S			Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]]	S	Oral	400 Milligram Daily;	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Reactine (Cetirizine)	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous drip		Not Reported
Sarilumab	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Stelara	S	Unknown		Not Reported
Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfathalidine	S	Unknown		Not Reported
Topicort	S	Unknown		Not Reported
Topicort	S	Subcutaneous		Not Reported
Xeljanz	S	Unknown	10 Milligram Daily;	Not Reported
Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C			Not Reported
Salazopyrina	C			Not Reported
Tofacitinib Citrate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17730288	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590432		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Sleep Disorder	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Otezla			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sirukumab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ustekinumab			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17730396	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590228			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia;	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Leflunomide	S	Unknown	Not Reported
	Meloxicam	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Mobicox	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Depomedrol	C	Intramuscular	Not Reported
	Diclofenac	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17730403	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012547			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Cimzia			S	Subcutaneous	Single Use Prefilled Syringe		Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Etanercept			S	Subcutaneous			Not Reported

	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil (Hydroxychloroquine Phosphate)	S	Unknown		Not Reported
	Prednisone	S	Oral		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	In Pre-Filled Syringe	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Subcutaneous		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17730404	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012542		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased;	Diclofenac			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported

Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Actemra	S	Unknown		Not Reported
	Apo Prednison	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Cimzia	S	Unknown	Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquin	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Prednison	S	Unknown		Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Unknown		Not Reported
	Salazopyrine	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported

Sulfathalidine	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Cortisone Acetate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17730483	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590245		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Injury; Lymphadenectomy; Malignant Melanoma; Rheumatoid Arthritis; Sensitivity To Weather Change; Toe Amputation	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Intravenous drip	365.0		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	731.0		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Restasis			C	Unknown	Emulsion		Not Reported
	Synthroid			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17730976	EXPEDITED (15-DAY)		HO	CA-ROCHE-2588779		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	11720121	EXPEDITED (15-DAY)		DS	CA-ROCHE-1657676			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Drug Ineffective; Foot Operation; Loss Of Consciousness; Mobility Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	12454121	EXPEDITED (15-DAY)		OT	CA-ROCHE-1771508		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Plaquenil (Hydroxychloroquine Sulfate)		Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 190 Days		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Estradiol			C	Unknown			Not Reported
	Xalatan			C	Ophthalmic	Solution Opthalmic		Not Reported
	Cosopt			C	Unknown	Eye Drops		Not Reported
	Furosemide			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported

Gravol Ginger	C				Not Reported
Zingiber Officinale	C				Not Reported
Estrogel	C				Not Reported
Calcium	C	Unknown			Not Reported
Potassium Chloride	C	Unknown			Not Reported
Morphine	C	Unknown	As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	12844829	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2016M1042716		66 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Atrial Flutter; Drug Interaction	Methotrexate			S		7.5 Mg, Cycle (10 Days)		Not Reported
	Methotrexate			S		15 Mg, Qw		Not Reported
	Hydroxychloroquine			S		200 Mg, Qd		Not Reported
	Certolizumab Pegol			S		200 Mg, Biweekly		Mylan
	Certolizumab Pegol			S		1 Df, Q21d		Mylan
	Bromazepam			C		Unk		Mylan
	Bromazepam			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	13216626	EXPEDITED (15-DAY)		OT	CA-ROCHE-1890689		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	13359948	EXPEDITED (15-DAY)		OT	CA-SA-2017SA042969		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Arava			S	Oral	Unk Unk, Qw		Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk Unk,Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Pregabalin			S	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk Unk, Unk		Not Reported
	Actemra			S	Unknown	640 Mg, Qw		Not Reported
	Actemra			S		640 Unk		Not Reported
	Actemra			S		640 Unk		Not Reported
	Apo-Cyclosporine			S	Oral	Unk Unk,Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg,Qw		Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Other	50 Mg, 1 In 1 Week		Not Reported
	Enbrel			S		50 Unk		Not Reported
	Enbrel			S		50 Mg For 4 Yrs		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qw		Not Reported
	Humira			S		40 Unk		Not Reported
	Humira			S		40 Mg, Qw For 4 Years		Not Reported
	Apo-Azathioprine			S	Unknown	Unk Unk,Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg		Not Reported

	Certolizumab	S	Subcutaneous	200 Mg, Qw	Not Reported
	Certolizumab	S		200 Unk	Not Reported
	Certolizumab	S		200 Mg For 9.0 Month(S) Unk	Not Reported
	Gold	S	Unknown	Unk Unk, Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Qw	Not Reported
	Infliximab	S		300 Mg, Qw For 2 Years	Not Reported
	Methotrexate Sodium	S	Unknown	Unk Unk, Unk	Not Reported
	Rituximab	S	Unknown	Unk Unk, Unk	Not Reported
	Orencia	S	Unknown	Unk Unk, Unk	Not Reported
	Simponi	S	Unknown	Unk Unk, Unk	Not Reported
	Azathioprine	S	Unknown		Not Reported
	Ciclosporin	S	Oral	Unk	Not Reported
	Prednisone	C			Not Reported
	Piroxicam	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	13657150	EXPEDITED (15-DAY)		HO, LT, OT	CA-SA-2017SA105823		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint	Sodium Aurothiomalate			S	Parenteral	Unk Unk,Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	Unk Unk,Unk		Not Reported
	Hydroxychloroquine			S		Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S	Oral	Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S		Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S		Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S		Unk Unk,Unk		Sanofi
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi

Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Leflunomide	S	Oral	Unk Unk,Unk	Sanofi
	Minocycline Hydrochloride	S			Not Reported
	Minocycline Hydrochloride	S			Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Arava	S			Sanofi
	Arava	S			Sanofi
	Leflunomide	S			Sanofi
	Leflunomide	S			Sanofi
	Hydroxychloroquine Sulfate	S			Sanofi
	Hydroxychloroquine Sulfate	S			Sanofi
	Plaquenil	S			Sanofi
	Plaquenil	S		400 Mg	Sanofi
	Oxycodone	S		10 Mg	Not Reported
	Actemra	S	Unknown	Unk Unk,Unk	Not Reported
	Actemra	S	Unknown	Unk Unk,Unk	Not Reported
	Anakinra	S	Unknown	Unk Unk,Unk	Not Reported
	Anakinra	S	Unknown	Unk Unk,Unk	Not Reported
	Humira	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Humira	S		Unk Unk,Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk Unk,Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk Unk,Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Remicade	S		Unk Unk,Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk Unk,Unk	Not Reported

Enbrel	S		Unk Unk,Unk		Not Reported
Marijuana	S				Not Reported
Xeljanz	S		Oral	Unk Unk, Bid	Not Reported
Gold	S				Not Reported
Ilaris	S		Subcutaneous	Unk Unk,Unk	Not Reported
Ilaris	S		Subcutaneous	Unk Unk,Unk	Not Reported
Hydroxychloroquine Phosphate	C		Unknown	Unk Unk,Unk	Not Reported
Rituximab	C			Unk	Not Reported
Anakinra	C			Unk	Not Reported
Lyrica	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	13868474	EXPEDITED (15-DAY)		OT	CA-ROCHE-1976526		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 730.0 Nos		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	15388757	EXPEDITED (15-DAY)		OT	CA-ROCHE-2182492		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Cortisone	S	Unknown	Not Reported
Apo-Folic Acid	S	Unknown	Not Reported
Apo-Folic Acid	S	Oral	Not Reported
Apo-Folic Acid	S	Unknown	Not Reported
Desoximetasone	S	Oral	Not Reported
Fosamax	S	Oral	Not Reported
Fosamax	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Topicorte	S	Subcutaneous	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Sarilumab	S	Unknown	Not Reported
Diclofenac Sodium	S	Unknown	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Leflunomide	S	Oral	Not Reported
Stelara	S	Unknown	Not Reported
Diclofenac	S	Unknown	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Not Reported
Paracetamol	S	Unknown	Not Reported

Actemra	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Topicort Lp	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Cetirizine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Golimumab	S	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	15897378	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-002605		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip	Topicort			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Bausch And Lomb
	Cortisone Acetate			S	Oral			Not Reported
	Desoximetasone			S	Cutaneous			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Hydrocortisone Acetate			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Actemra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Oral		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Sunconjunctival		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Plaquenil	S	Unknown		Not Reported

Prednisone	S	Unknown		Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Therapy Duration 365 (Unspecified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Oral	Therapy Duration: 365 (Unspecified)	Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Cetirizine Hydrochloride	S	Unknown		Not Reported
Cetirizine Hydrochloride	S	Unknown		Not Reported
Cetirizine Hydrochloride W/Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Paracetamol	S	Unknown		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Sarilumab	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Apo Folic	S	Unknown		Not Reported
Apo Hydroxyquine	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Stelara	S	Unknown		Not Reported

	Sulfathalidine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	16066887	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1022788		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Off Label Use; Pruritus; Rash Maculo-Papular	Repaglinide			S	Oral	Unk		Not Reported
	Coversyl /00790702/			S	Oral	Unk		Mylan
	Coversyl /00790702/			S	Unknown	Unk Unk,Unk		Mylan
	Plaquenil /00072603/			S	Oral	200 Mg/ Day		Mylan
	Cortancyl			S	Oral	10-20µg		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	16217782	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190424225		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Hair Follicle Tumour Benign; Lymphoproliferative Disorder; Off Label Use; Product Use In Unapproved Indication	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Remicade			S				Not Reported
	Acetazolamide			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Azathioprine			S				Not Reported
	Calcium Carbonate			S	Unknown			Not Reported
	Cyclosporine			S	Unknown			Not Reported
	Cyclosporine			S				Not Reported
	Ferric Hydroxide Polymaltose Complex			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Leflunomide	S		Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S		Not Reported
Methotrexate	S		Not Reported
Amlodipine	S	Unknown	Not Reported
Cyclophosphamide	S	Unknown	Not Reported
Enalapril	S	Unknown	Not Reported
Ferrous Fumarate	S	Unknown	Not Reported
Insulin	S	Unknown	Not Reported
Metformin	S	Unknown	Not Reported
Nutropin	S	Subcutaneous	Not Reported
Prednisone	S	Unknown	Not Reported
Protropin	S	Intramuscular	Not Reported
Ranitidine	S	Unknown	Not Reported
Sulfamethoxazole	S	Unknown	Not Reported
Testosterone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	16693247	EXPEDITED (15-DAY)		OT	CA-SA-2019SA208351		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic	Arava			S	Oral	Unk Unk, Unk		Sanofi
	Plaquenil			S	Oral	400 Mg, Unk		Sanofi
	Hydroxychloroquine			S	Unknown	400 Mg		Sanofi
	Hydroxychloroquine Sulfate			S		400 Mg		Sanofi
	Methotrexate			S	Unknown	25 Mg, Qw		Not Reported
	Codeine			S	Unknown	Unk Unk, Unk		Not Reported
	Actemra			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Adalimumab			S	Unknown	Unk Unk, Unk		Not Reported
	Anakinra			S	Unknown	Unk Unk, Unk		Not Reported

Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Cimzia	S	Subcutaneous	Unk Unk, Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk Unk, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk, Unk	Not Reported
	Simponi	S	Subcutaneous	50 Mg, Qm	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Prednisone	C	Unknown	30 Mg, Qw	Not Reported
	Prednisone	C		35 Mg, Qd	Not Reported
	Xeljanz	C	Unknown	Unk Unk, Unk	Not Reported
	Simponi	C	Subcutaneous	50 Mg	Not Reported
	Adalimumab	C		Unk	Not Reported
	Sulfasalazine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	16693818	EXPEDITED (15-DAY)		OT	CA-SA-2019SA208304		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Arava			S	Oral	Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk Unk, Unk		Not Reported
	Pregabalin			S	Unknown	Unk Unk, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Actemra			S		640 Mg, Unk		Not Reported

Actemra	S		640 Mg, Unk	Not Reported
Actemra	S		640 Mg, Qw	Not Reported
Apo-Azathioprine	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk Unk, Unk	Not Reported
Certolizumab Pegol	S	Unknown	200 Mg For 9.0 Month(S)	Not Reported
Certolizumab Pegol	S	Unknown	200 Mg For 9.0 Month(S)	Not Reported
Ciclosporin	S	Oral	Unk Unk, Unk	Not Reported
Ciclosporin	S	Oral		Not Reported
Ciclosporin	S	Oral		Not Reported
Cimzia	S	Subcutaneous	200 Mg, Single-Use Prefilled Syringe	Not Reported
Cimzia	S	Subcutaneous	200 Mg Qw, Single-Use Prefilled Syringe	Not Reported
Enbrel	S	Unknown	50 Mg, Qw	Not Reported
Enbrel	S	Unknown	50 Mg, Qw	Not Reported
Enbrel	S	Unknown	50 Mg, Unk For 4 Years	Not Reported
Gold	S	Unknown	Unk Unk, Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Qw For 4 Years	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Unknown	400 Mg, Qw	Not Reported
Imuran [Azathioprine Sodium]	S	Unknown	Unk Unk, Unk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Qw For 2 Years	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
Orencia	S	Unknown	Unk Unk, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
Simponi	S	Unknown	Unk Unk, Unk	Not Reported
Rituxan	S	Unknown	Unk Unk, Unk	Not Reported
Piroxicam	C			Not Reported

Prednisone	C	Unk Unk, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	16731220	EXPEDITED (15-DAY)		DE, HO, OT	CA-TEVA-2019-CA-1095844		16 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Clear Cell Renal Cell Carcinoma; Complications Of Bone Marrow Transplant; Hair Follicle Tumour Benign; Hepatosplenic T-Cell Lymphoma; Hypotension; Lymphoproliferative Disorder; Off Label Use; Product Use In Unapproved Indication; Product Use Issue; Pyrexia; Splenomegaly; T-Cell Lymphoma; Tachycardia; Thrombocytopenia	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Ciclosporin			S	Unknown			Ivax
	Ciclosporin			S				Ivax
	Etoposide			S	Unknown			Teva
	Etoposide			S				Teva
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	.7143 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S				Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Thalidomide			S	Oral			Not Reported
	Etanercept			S	Unknown			Not Reported
	Etanercept			S				Not Reported
	Kineret 100mg Per Syringe Single-Use,Preservative-Free Prefilled Syrin			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	33.3333 Milligram Daily;		Not Reported
	Remicade			S				Not Reported
	Acetazolamide			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Actavis
	Amlodipine			S	Unknown			Teva
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported

Azathioprine	S		Not Reported
Calcium Carbonate	S	Unknown	Not Reported
Cyclophosphamide	S	Unknown	Not Reported
Enalapril	S	Unknown	Not Reported
Ferric Hydroxide Polymaltose Complex	S	Unknown	Not Reported
Ferrous Fumarate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Insulin	S	Unknown	Not Reported
Leflunomide	S	Unknown	Barr
Leflunomide	S		Barr
Metformin	S	Unknown	Actavis
Nutropin	S	Subcutaneous	Not Reported
Prednisone	S	Unknown	Actavis
Protropin	S	Intramuscular	Not Reported
Ranitidine	S	Unknown	Not Reported
Sulfamethoxazole	S	Unknown	Not Reported
Testosterone	S	Unknown	Not Reported
Erelzi 25 Mg Solution For Injection In Prefilled Syringe	S	Subcutaneous	Not Reported
Etoposide	C		Not Reported
Kineret 100mg Per Syringe Single-Use,Preservative-Free Prefilled Syrin	C		Not Reported
Tacrolimus	C		Not Reported
Thalidomide Celgene -50 Mg Capsula Rigida - Celgene Europe Limited	C		Not Reported
Thalomid	C		Not Reported
Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	16805798	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201908000239			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaemia; Eye Haemorrhage; Weight Increased	Hydroxychloroquine	S	Unknown	Unk	Concordia
	Dupixent	S	Subcutaneous	Unk Loading Dose	Not Reported
	Dupixent	S	Subcutaneous	300 Mg, Qow	Not Reported
	Dupilumab Pre-Filled Syringe	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17027053	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA305395		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Triamcinolone Acetonide			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg/M2, Qow		Not Reported
	Hydroxychloroquine			S	Oral	5 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Oral	5 Mg, Qd		Sanofi
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			S		1.3 Unk		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Qw		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qw		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Qow		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	Unk, Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	5 Mg, Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 G, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Mg, Qm		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17033136	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-SA-2019SA308981		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present; Gastroenteritis Viral; Human Anti-Human Antibody Test; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Product Use Issue; Psoriasis; Pyrexia; Red Blood Cell	Triamcinolone Acetonide			S		Unk		Sanofi
	Triamcinolone Acetonide			S				Sanofi
	Triamcinolone Acetonide			S		Unk		Sanofi
	Triamcinolone Acetonide			S		Unk		Sanofi
	Triamcinolone Acetonide			S	Intra-articular	Unk		Sanofi
	Hydroxychloroquine			S	Oral	5 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Oral	5 Mg/Kg, Qd		Sanofi
	Hydroxychloroquine			S	Oral	Unk		Sanofi
	Naproxen			S		Unk		Not Reported
	Naproxen			S	Oral	3 Mg, Qd		Not Reported
	Naproxen			S	Oral	5 Mg, Qd		Not Reported
	Naproxen			S	Unknown	Unk Unk, Unk		Not Reported
	Naproxen			S				Not Reported
	Prednisone			S	Oral	1.3 Mg, Bid		Not Reported
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S	Oral	50 Mg, Bid		Not Reported
	Prednisone			S		50 Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			S	Oral	1.3 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Sulfasalazine			S				Not Reported
	Methotrexate			S	Subcutaneous	15 Mg/M2, Qw		Not Reported
	Methotrexate			S		Unk Unk, Qw		Not Reported

Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Methotrexate	S	Subcutaneous	Unk Unk, Qw	Not Reported
	Methotrexate	S		Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Qow	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	70 G	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	70 G	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	70 G	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg/Kg, Q6w	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Mg	Not Reported
	Infliximab	S		Unk Unk, Qw	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unk, Q6w	Not Reported
	Kineret	S	Subcutaneous	50 Mg, Qd	Not Reported
	Kineret	S	Subcutaneous	Unk Unk, Qd	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Qm	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Qm	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk Unk, Qm	Not Reported
	Orencia	S	Intravenous drip	250 Mg, Q2m	Not Reported
	Orencia	S	Intravenous drip	250 Mg, Qm	Not Reported

Orencia	S	Intravenous drip	250 Mg, Qm	Not Reported
Orencia	S	Respiratory (inhalation)	250 Mg, Qm	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Unk	Not Reported
Orencia	S		Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S		Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qw	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qow	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qod	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qow	Not Reported
Etanercept	S	Subcutaneous	12.5 Mg, Qw	Not Reported
Etanercept	S	Subcutaneous	25 Mg, Biw	Not Reported
Enbrel	S	Subcutaneous	25 Mg, Qw	Not Reported
Enbrel	S	Subcutaneous	12.5 Mg, Qw	Not Reported
Enbrel	S	Subcutaneous	25 Mg, Qow	Not Reported
Enbrel	S	Subcutaneous	12.5 Mg, Qw	Not Reported
Enbrel	S	Subcutaneous	25 Mg	Not Reported
Abatacept	S	Intravenous drip	250 Mg, Qm	Not Reported
Adalimumab	S	Subcutaneous		Not Reported
Adalimumab	S		Unk	Not Reported

Anakinra	S	Subcutaneous	50 Mg, Qw		Not Reported
Anakinra	S	Subcutaneous	50 Mg, Qd		Not Reported
Anakinra	S		50 Unk		Not Reported
Anakinra	S	Subcutaneous	Unk		Not Reported
Anakinra	S	Subcutaneous	50 Mg, Qd		Not Reported
Anakinra	S		Unk		Not Reported
Orencia	S				Not Reported
Orencia	S	Intravenous drip	250 Mg, Qm		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Qow		Not Reported
Folic Acid	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17069951	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201911001908			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Bacterial Infection; Contusion; Cystitis; Fatigue; Feeling Abnormal; Hemiparesis; Hysterectomy; Insomnia; Pain; Pain In Extremity; Ph Body Fluid Abnormal; Pyrexia; Tremor; Vaginal Haemorrhage; Vulvovaginal Mycotic Infection	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Teriflunomide			S	Oral	14 Mg, Qd (Coated Tablet)		Not Reported
	Teriflunomide			S	Oral	14 Mg, Qd		Not Reported
	Fludrocortisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17419878	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543667		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug	Actemra			S	Unknown			Not Reported

Ineffective; Rheumatoid Arthritis; Synovitis; Treatment Failure	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Meloxicam	C	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17653955	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-017958		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Levofloxacin			S	Unknown	Unk		Aurobindo
	Lopinavir;Ritonavir			S	Oral	2 Dosage Form, Two Times A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Once A Day		Not Reported
	Tacrolimus			S	Oral	Unk		Not Reported
	Enoxaparin Sodium			C	Subcutaneous	40 Milligram, Once A Day		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Prednisone			C	Oral	20 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17716072	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-020311		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Electrocardiogram Qt Prolonged; Long Qt Syndrome; Sudden Death	Azithromycin	S	Oral	500 Milligram, Once A Day	Aurobindo
	Salbutamol	S	Respiratory (inhalation)	0.1 Milligram, Four Times/Day	Not Reported
	Dolquine	S	Oral	400 Milligram, Two Times A Day	Not Reported
	Propofol	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Metoclopramide	S	Intravenous (not otherwise specified)	10 Milligram, 3 Times A Day	Not Reported
	Ipratropium Bromide	C	Respiratory (inhalation)	20 Microgram, Four Times/Day	Not Reported
	Enoxaparin Sodium	C	Subcutaneous	Unk	Not Reported
	Cefotaxime	C	Intravenous drip	4 Gram, Two Times A Day	Not Reported
	Midazolam	C	Intravenous drip	100 Milligram, Once A Day	Not Reported
	Tocilizumab	C	Intravenous (not otherwise specified)	600 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17721946	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1227338		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported
	Dolquine			S	Oral	400 Milligram Daily; Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17724166	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020166893		41 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17731644	EXPEDITED (15-DAY)		HO, LT, OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-245540		36 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased	Tacrolimus			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sun
	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported
	Cobicistat/Darunavir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17731661	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004004082			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dizziness; Ear Pain; Eye Injury; Headache; Herpes Virus Infection	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17731724	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202004004144			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Respiratory Distress Syndrome; Hepatocellular Injury; Off Label Use	Hydroxychloroquine	S	Oral	400 Mg, Qd, Film-Coated Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17731781	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589712		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17731830	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588725			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17731867	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588961		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Neoral	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17732413	EXPEDITED (15-DAY)		HO	CA-ROCHE-2587291		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abscess; Adrenal Insufficiency; Alanine Aminotransferase Increased; Ascites; Asthenia; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Potassium Decreased; Blood Pressure Diastolic Abnormal; Blood Pressure Increased; Congestive Hepatopathy; Depression; Diverticulitis; Endometrial Disorder; Enterococcus Test Positive; Fibrosis;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Ceftazidime			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Piperacillin Sodium;Tazobactam Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rosuvastatin Calcium			S	Unknown			Not Reported
	Vancomycin			S	Unknown			Not Reported

Gamma-Glutamyltransferase Increased; Gastrointestinal Disorder; Generalised Oedema; Heart Rate Increased; Herpes Zoster; Hypersensitivity; Hypoglycaemia; Hypotension; Increased Appetite; Influenza; Infusion Related Reaction; Injection Site Extravasation; Intensive Care Unit Acquired Weakness; Intervertebral Disc Protrusion; Joint Effusion; Joint Swelling; Micturition Disorder; Myelopathy; Myopathy; Nasopharyngitis; Nausea; Nerve Compression; Neuropathy Peripheral; Neutropenia; Osteoarthritis; Pancytopenia; Peripheral Sensorimotor Neuropathy; Peritonitis; Pneumonia; Pseudomonal Bacteraemia; Rheumatoid Arthritis; Septic Shock; Therapeutic Response Decreased; Vomiting; Weight Decreased; Weight Increased	Acetaminophen	C	Unknown	Not Reported
	Actonel	C	Unknown	Not Reported
	Apo Amlo	C	Unknown	Not Reported
	Apo-K	C	Unknown	Not Reported
	Diphenhydramine Hydrochloride	C	Unknown	Not Reported
	Epoetin Alfa	C	Unknown	Not Reported
	Escitalopram	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Insulin Lispro	C	Unknown	Not Reported
	Januvia	C	Unknown	Not Reported
	Kcl	C	Unknown	Not Reported
	Metformin	C	Unknown	Not Reported
	Methylprednisolone	C	Unknown	Not Reported
	Metoprolol	C	Unknown	Not Reported
	Pantoloc [Pantoprazole]	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Risedronate	C	Unknown	Not Reported
	Slow-K	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Ventolin [Salbutamol]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17732433	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589459		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel	Actemra			S	Unknown			Not Reported

Syndrome; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Knee Arthroplasty; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Apo-Leflunomide	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Methotrexate	S	Unknown	Duration 4 Month		Not Reported
	Methotrexate	S	Unknown	Duration 4 Month		Not Reported
	Orencia	S	Unknown	Duration 4 Month		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Duration 4 Month		Not Reported
	Prednisone	S	Unknown	Duration 4 Month		Not Reported
	Remicade	S	Unknown	Duration 4 Month		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Duration 4 Month		Not Reported
	Simponi	S	Subcutaneous	Duration 4 Month		Not Reported
	Xeljanz	S	Oral	Duration 4 Month		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17732474	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202004003662			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17732521	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202004002893			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17732732	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588738			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17732774	EXPEDITED (15-DAY)		OT	CA-ROCHE-2587807		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis	Arava	S	Oral	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Ciclosporin	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17733312	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1229092		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance;	Ciclosporin			S	Unknown			Ivax
	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr

Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Azathioprine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17733315	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1229034		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Jaw; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17733337	EXPEDITED (15-DAY)		HO	ES-BAYER-2020-066313		49 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Hepatitis; Hypokalaemia	Betaferon			S	Subcutaneous	0.25 Mg		Bayer
	Betaferon			S				Bayer
	Dolquine			S	Oral	400 Mg Dia		Not Reported

	Kaletra	S	Oral	2 Df, Bid		Not Reported
	Kaletra	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17733717	EXPEDITED (15-DAY)		OT	US-ABBVIE-20K-163-3387130-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Systemic Lupus Erythematosus	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17733894	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588759			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical Device Implantation	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17734070	NON-EXPEDITED		HO, OT	PL-AMGEN-POLSP2020070504		35 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis Of Pregnancy; Erythema Nodosum;	Enbrel			S	Unknown	Unk		Amgen

Maternal Exposure During Pregnancy; Normal Newborn; Ultrasound Scan Abnormal	Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
	Encorton [Prednisone Acetate]	S	Unknown	15 Milligram, Qd	Not Reported
	Encorton [Prednisone Acetate]	S	Unknown	10 Milligram, Qd	Not Reported
	Plaquenil S	S	Unknown	20 Milligram, Qd	Not Reported
	Erelzi [Etanercept]	S	Intravenous (not otherwise specified)	50 Milligram	Not Reported
	Erelzi [Etanercept]	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Erelzi [Etanercept]	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Benepali	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Metex [Methotrexate Sodium]	C	Subcutaneous	Unk (The Last Injection In Jan-2019))	Not Reported
	Folic Acid	C		Unk	Not Reported
	Insulin	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17734176	EXPEDITED (15-DAY)		DE, OT	CH-SA-2020SA109443		72 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolytic Anaemia; Off Label Use; Thrombocytopenia; Thrombotic Microangiopathy	Plaquenil			S	Oral	800 Mg/Day From 22 To 23 Mar 2020, 400 Mg/Day From 24 To 26 Mar 2020, 600 Mg/Day From 26 To 30 Mar 2		Sanofi
	Plaquenil			S				Sanofi
	Doxycycline			S	Oral	200 Mg		Not Reported
	Azithromycin			S	Oral	250 Mg		Not Reported
	Amoxicillin Trihydrate/Potassium Clavulanate			S	Intravenous drip	3.6 G, Qd		Not Reported
	Enoxaparin Sodium			S	Subcutaneous	40 Mg		Sanofi
	Fentanyl			S	Transdermal	25 Ug/H		Not Reported
	Piperacillin + Tazobactam			C	Intravenous (not	13.5 G		Not Reported

			otherwise specified)	
	Paracetamol	C	500 Mg, Qid	Not Reported
	Paracetamol	C	500 Mg	Not Reported
	Humulus Lupulus Extract;Valeriana Officinalis Extract	C		Not Reported
	Macrogol	C	Unk Unk, Qd	Not Reported
	Metoclopramide	C	10 Mg, Tid	Not Reported
	Relaxane	C	Unk Unk, Tid	Not Reported
	Supradyn [Minerals Nos;Vitamins Nos]	C	Unk Unk, Qd	Not Reported
	Redormin [Remifentanil Hydrochloride]	C	500 Mg, Qd	Not Reported
	Dexamethasone	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17734253	EXPEDITED (15-DAY)		OT	CA-SA-2020SA112718		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Desoximetasone			S	Oral	Unk		Sanofi
	Cortisone Acetate			S		Unk		Not Reported
	Alendronate Sodium			S		Unk		Not Reported
	Arava			S		Unk		Sanofi
	Cetirizine Hydrochloride			S	Unknown	10 Mg		Not Reported
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Methotrexate			S		20 Mg, Qd		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg		Sanofi
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Sanofi

Sulfasalazine	S	Oral	1000 Mg		Not Reported
Actemra	S	Unknown	Unk		Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	Unk		Not Reported
Cimzia	S	Subcutaneous	Unk		Not Reported
Enbrel	S	Subcutaneous	Unk		Not Reported
Golimumab	S		Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Unknown	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfathalidine	S	Unknown	Unk		Not Reported
Diclofenac	C		Unk		Not Reported
Salazopyrin	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17734523	EXPEDITED (15-DAY)		LT, OT	FR-PFIZER INC-2020171826		79 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Torsade De Pointes; Ventricular Arrhythmia	Zithromax			S	Other	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Other	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17734550	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020171235		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Loss Of Consciousness; Malaise; Off Label Use; Product Use In Unapproved Indication; Ventricular Extrasystoles	Azithromycin			S	Oral	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			C		Unk		Not Reported
	Paracetamol			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17734833	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589482			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Oral			Not Reported
	Zyrtec-D			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported

Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous drip	Not Reported
Sarilumab	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Stelara	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Topicorten	S	Subcutaneous	Not Reported
Xeljanz	S	Unknown	Not Reported
Desoximetasone	S	Unknown	Not Reported
Desoximetasone	S	Unknown	Not Reported
Folic Acid	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17734929	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1042716			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Nightmare; Product Use In Unapproved Indication; Psychomotor Hyperactivity	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Plaquenil /00072602/			S	Oral	600 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17735719	EXPEDITED (15-DAY)		DS, OT	CA-BAUSCH-BL-2020-012941		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Live Birth; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Desoximetasone			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Cortisone Acetate			S	Oral			Not Reported
	Cortisone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Topicort			S	Subcutaneous			Not Reported
	Topicort			S	Unknown			Not Reported
	Topicort			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo Prednison			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Oral			Not Reported

Folic Acid	S	Oral	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Fosamax	S	Oral	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Leflunomide Sandoz	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Methotrexate Sodium	S	Subcutaneous	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Paracetamol	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Not Reported
Plaquenil	S	Unknown	Not Reported

Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sarilumab	S	Unknown	Not Reported
Sarilumab	S	Unknown	Not Reported
Simponi	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Not Reported
Stelara	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Sulfathalidine	S	Subcutaneous	Not Reported
Tofacitinib Citrate	S	Subcutaneous	Not Reported
Tofacitinib Citrate	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Cortisone Acetate	S	Topical	Not Reported
Acetaminophen	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported

	Atasol	C	Unknown		Not Reported
	Salazopyrin	C	Unknown		Not Reported
	Tofacitinib Citrate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17735914	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-02			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Tenosynovitis; Treatment Failure	Mobicox			S	Oral			Boehringer Ingelheim
	Cosentyx			S	Oral			Not Reported
	Diclofenac			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leucovorin Calcium			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Otezla			S	Unknown			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Pantoprazole Magnesium			S	Unknown			Not Reported
	Synthroid			S	Unknown			Not Reported
	Diltiazem Hydrochloride			C	Oral			Not Reported
	Fluticasone Propionate			C	Respiratory (inhalation)			Not Reported
	Mar-Pantoprazole			C	Unknown	Tablet (Delayed Release)		Not Reported
	Mometasone Furoate			C	Unknown			Not Reported
	Premarin			C	Unknown			Not Reported
	Salbutamol Sulfate			C	Respiratory			Not Reported

			(inhalation)	
	Tramadol Hydrochloride	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17736149	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2020176534			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rectal Cancer	Xeljanz Xr			S		11 Mg, 1x/Day (11mg Qd)		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17736216	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012554			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling;	Cortisone Acetate			S	Unknown			Not Reported
	Cortisone			S	Oral			Not Reported
	Cortisone			S	Unknown			Not Reported
	Topicort			S	Unknown			Not Reported
	Topicort			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Oral	Not Reported
	Fosamax	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Golimumab	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Unknown	Not Reported

	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Topicort	S	Subcutaneous	Not Reported
	Atasol	C		Not Reported
	Salazopyrina	C		Not Reported
	Tofacitinib Citrate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17736256	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-02			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Tenosynovitis; Treatment Failure	Mobicox			S	Oral			Boehringer Ingelheim
	Cosentyx			S	Oral			Not Reported
	Diclofenac			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leucovorin Calcium			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Otezla			S	Unknown			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Pantoprazole Magnesium			S	Unknown			Not Reported
	Synthroid			S	Unknown			Not Reported
	Premarin			C	Unknown			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported

Salbutamol Sulfate	C	Respiratory (inhalation)			Not Reported
Mometasone Furoate	C	Unknown			Not Reported
Mar-Pantoprazole	C	Unknown	Form Of Admin: Tablet (Delayed-Release)		Not Reported
Fluticasone Propionate	C	Respiratory (inhalation)			Not Reported
Diltiazem Hydrochloride	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17736716	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-021403		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day(Dia)		Aurobindo
	Azithromycin			S				Aurobindo
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day(Dia)		Not Reported
	Hydroxychloroquine			S				Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram		Not Reported
	Tocilizumab			S				Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day(Dia)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17736737	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-093087		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Risedronate Tablet			S	Unknown	35 Milligram, Every Week		Aurobindo
	Hydroxychloroquine Sulfate			S	Unknown	1 Dosage Form, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Once A Day		Not Reported

	Leflunomide	S	Unknown	20 Milligram, Once A Day	Not Reported
	Leflunomide	S	Unknown	1 Dosage Form	Not Reported
	Actonel	S	Unknown	35 Milligram, Every Week	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	17.5 Milligram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	300 Milligram, Once A Day	Not Reported
	Hydroxychloroquine	C	Unknown	300 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17736746	EXPEDITED (15-DAY)		HO, LT, OT	ES-AUROBINDO-AUR-APL-2020-021570		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia; Pancreatitis Acute	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Ceftriaxona			S	Intravenous (not otherwise specified)	1 Gram, Once A Day		Not Reported
	Dolquine			S	Oral	200 Milligram, Two Times A Day		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Two Times A Day		Not Reported
	Metilprednisolona			S	Intravenous (not otherwise specified)	250 Milligram, Once A Day		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	560 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	15369646	EXPEDITED (15-DAY)		OT	CA-ROCHE-2181868		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Hepatic Enzyme Increased; Joint Swelling; Liver Disorder; Mesenteritis; Oedema Peripheral; Pyrexia	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	16139048	EXPEDITED (15-DAY)		OT	DE-ACCORD-117446		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Methotrexate			S	Subcutaneous	20 Mg, Tablet Oral		Accord
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg, Powder For Solution Intravenous		Not Reported
	Leflunomide			S		Film-Coated Tablet		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Apo-Leflunomide			S	Oral	Also Received Additionally, Film Coated Tablet		Not Reported
	Ciclosporin			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported

Apo-Hydroxyquine	S	Subcutaneous	Also Received Oral Tablet		Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
Apo-Hydroxyquine	S	Oral	Unk, Also Received Subcutaneous Apo-Hydroxyquine Thrice		Not Reported
Rituxan	S	Unknown	Solution Intravenous		Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Xeljanz	C	Oral	10 Mg, Qd (5 Mg, Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17736773	EXPEDITED (15-DAY)		HO	ES-AUROBINDO-AUR-APL-2020-021363		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hyponatraemia	Levofloxacin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Kaletra			S	Oral	2 Dosage Form (2u/2 H)		Not Reported
	Kaletra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17736776	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-019740		77 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Thrombocytopenia	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Clexane			S	Subcutaneous	4 Kilo-International Unit, Once A Day		Not Reported
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17736804	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-		56 YR	Male	FRA

APL-2020-020847

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Olanzapine			S	Oral	7.5 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	800 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17736808	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2020-020857			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation; Off Label Use	Azithromycin			S	Unknown	Unk		Aurobindo
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17736838	EXPEDITED (15-DAY)		HO	ES-HETERO-HET2020ES00483		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hyponatraemia	Levofloxacin			S	Oral	500 Mg, Qd		Hetero
	Dolquine			S	Oral	400 Mg, Qd		Not Reported
	Kaletra			S	Oral	12 Hours Bid (200/50mg)		Not Reported
	Kaletra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17736861	EXPEDITED (15-DAY)		OT	CA-ROCHE-2587376		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use;	Actemra			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17736873	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-020465		82 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Haloperidol			S	Oral	5 Gtt Drops, Once A Day		Not Reported
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported
	Teicoplanin			S	Intravenous (not otherwise specified)	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17736886	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR-1228537		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cholestasis; Condition Aggravated; Hepatocellular Injury	Azithromycine Anhydre	S	Oral	250 Mg		Not Reported
	Plaquenil	S	Oral	600 Mg		Not Reported
	Rocephine	S	Oral	2 G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17737066	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-PBT-000161			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Tacrolimus			S	Transplacental	From Gestational Week 0-14		Panacea Biotec
	Tacrolimus			S	Transplacental	From Gestational Week 0-14		Panacea Biotec
	Tacrolimus			S	Transplacental	From Gestational Week 0-14		Panacea Biotec
	Tacrolimus			S	Transplacental			Panacea Biotec
	Heparin			S	Transplacental			Not Reported
	Prednisolone			S	Transplacental	From Gestational Week 0-14		Not Reported
	Prednisolone			S	Unknown			Not Reported
	Torasemide			S	Transplacental	From Gestational Week 0-14		Not Reported
	Torasemide			S	Transplacental			Not Reported
	Hydroxychloroquine Sulfate			S	Transplacental	From Gestational Week 0-14		Not Reported
	Hydroxychloroquine Sulfate			S	Transplacental			Not Reported
	Dalteparin Sodium			S	Transplacental			Not Reported
	Simvastatin			S	Transplacental	From Gestational Week 0-14		Not Reported
	Simvastatin			S	Transplacental			Not Reported
	Clexane			S	Transplacental	From Gestational Week 0-14, 200 Mg/D (2x100)		Not Reported
	Salbutamol Sulfate			S	Transplacental	From Gestational Week 0-		Not Reported

			14	
Salbutamol Sulfate	S	Transplacental		Not Reported
Acetylsalicylic Acid	S	Transplacental	From Gestational Week 0-14	Not Reported
Acetylsalicylic Acid	S	Transplacental		Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported
Xarelto	S	Transplacental	From Gestational Week 0-5	Not Reported
Xarelto	S	Transplacental		Not Reported
Pantoprazole	S	Transplacental	40 [Mg/D]; 0-13.6 Gestational Week	Not Reported
Pantoprazole	S	Transplacental	From Gestational Week 0-14	Not Reported
Pantoprazole	S	Transplacental	From Gestational Week 0-14	Not Reported
Ezetimibe	S	Transplacental	From Gestational Week 0-14	Not Reported
Ezetimibe	S	Transplacental		Not Reported
Nicotine	S	Transplacental	From Gestational Week 0-14	Not Reported
Nicotine	S	Transplacental		Not Reported
Ramipril	S	Transplacental	20 Mg, Qd From Gestational Week 0-113+6	Not Reported
Ramipril	S	Transplacental	Maternal Dose 20 Mg, Unk	Not Reported
Aliskiren	S	Transplacental	300 [Mg/D]; 0-4.6 Gestational Week	Not Reported
Aliskiren	S	Transplacental		Not Reported
Aliskiren	S	Transplacental		Not Reported
Metamizole Sodium	S	Transplacental	From Gestational Week 0-14	Not Reported
Metamizole Sodium	S	Transplacental		Not Reported

	Misoprostol	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
	Novaminsulfon	S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5	Not Reported
	Cyclophosphamide	C	Transplacental	3000 [Mg Cumulative]; Preconceptional	Not Reported
	Mifepristone	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
	Enoxaparin Sodium	S	Transplacental	(From Gestational Week 0-14)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17737105	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230648			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Intolerance; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Ciclosporin			S	Unknown			Ivax
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous	25 Mg, 1 Every 1 Week		Barr
	Actemra			S	Subcutaneous			Not Reported
	Azathioprine			S	Subcutaneous			Not Reported
	Azathioprine			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Kevzara			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Magnesium			C				Not Reported

	Metformin	C	Unknown		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17737108	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1229118		61 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Drug Interaction; Hypofibrinogenaemia; Melaena; Sepsis	Hidroxicloroquina (2143a)			S	Oral			Teva
	Hidroxicloroquina (2143a)			S				Teva
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab (8289a)			S				Not Reported
	Dexametasona (722a)			C	Intravenous (not otherwise specified)			Not Reported
	Dexametasona (722a)			C	Intravenous (not otherwise specified)	20mg/24h Los Primeros 5 Dias, Posteriormente 10 Mg/24h Durante 5 Dias Más.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17737152	EXPEDITED (15-DAY)		DE, OT	DE-TEVA-2020-DE-1229088		82 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Off Label Use	Hydroxychloroquine			S	Oral	400 Milligram Daily; 1-0-1		Teva
	Hydroxychloroquine			S				Teva
	Azithromycin			C				Not Reported
	Azithromycin			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17737198	EXPEDITED (15-DAY)		LT	FR-TEVA-2020-FR-1229150		56 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Electrocardiogram Qt Prolonged	Olanzapine	S	Oral	7.5 Mg		Teva
	Plaquenil 200 Mg, Comprime Pellicule	S	Oral	800mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2020	14308678	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050900		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Etanercept			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S		Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Weekly (Qw)		Not Reported
	Methotrexate			C	Oral	25 Mg, Weekly (Qw)		Not Reported
	Plaquenil			C		200 Mg, 2x/Day (Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2020	17737230	EXPEDITED (15-DAY)		HO	CA-ROCHE-2590268		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2020	17737254	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590321		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Vasculitic Rash	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2020	17737289	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589205			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2020	17737294	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020017839		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Enbrel			S		50 Milligram		Not Reported
	Enbrel			S		Unk		Not Reported

Humira	S	Subcutaneous	40 Milligram, Solution		Not Reported
Hydroxychloroquine Sulfate	S				Not Reported
Kevzara	S				Not Reported
Leflunomide	S				Not Reported
Methotrexate	S	Oral			Not Reported
Methotrexate	S	Subcutaneous	Unk		Not Reported
Orencia	S				Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Sarilumab	S				Not Reported
Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S				Not Reported
Tocilizumab	S				Not Reported
Xeljanz	S	Oral	5milligram, 2 Every 1 Days		Not Reported
Rabeprazole Sodium	C	Oral	20 Milligram, Once Daily (Qd)		Not Reported
Folic Acid	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2020	17737316	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020161825		40 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	12182291	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1723643		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Sleep Disorder; Therapeutic Product Effect Decreased;	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous	Therapy Duration: 2.0		Not Reported

Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Viral Infection				Month(S)	
	Enbrel	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Urethral		Not Reported
	Methotrexate Sodium	S	Oral	(2.5 Mg- 8 Tablets Orally Once Weekly)	Not Reported
	Methotrexate Sodium	S	Unknown	Solution For Injection	Not Reported
	Methotrexate Sodium	S	Oral	Therapy Duration: 24.0 Year(S)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Methotrexate	S	Oral	Therapy Duration 24.0 Years	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown	Solution For Injection	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Cymbalta	C			Not Reported
	Methotrexate	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	12891950	EXPEDITED (15-DAY)		HO, LT, OT	CA-APOPHARMA INC-2016AP013468			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S				Apotex

Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Leflunomide	S	Unknown	Unk	Apotex
	Leflunomide	S	Oral	Unk	Apotex
	Apo-Leflunomide	S	Unknown	Unk	Apotex
	Apo-Leflunomide	S			Apotex
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S			Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S			Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Ilaris	S	Unknown	Unk Unk, Unknown	Not Reported
	Ilaris	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S			Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported

	Plaquenil /00072602/			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	13054285	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015721			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Oral	10 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	200 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Actemra			C	Subcutaneous	Unk		Not Reported
	Enbrel			C	Subcutaneous	Unk		Not Reported
	Humira			C	Unknown	40 Mg, Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Orencia			C	Unknown	Unk		Not Reported
	Remicade			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			C	Intravenous (not	Unk		Not Reported

			otherwise specified)			
	Arava	C	Unknown	Unk		Not Reported
	Prednisone	C	Unknown			Not Reported
	Simponi	C	Unknown	Unk		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	13058845	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015768		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Off Label Use; Red Blood Cell Sedimentation Rate Increased; Urticaria	Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk, Q.Wk.		Not Reported
	Gold			S	Unknown	Unk, Qd		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	22.5 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S				Not Reported
	Methotrexate			S	Oral	22.5 Mg, Q.Wk.		Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S	Parenteral	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Parenteral	25 Mg, 1 Every 4 Weeks		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Adalimumab	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil /00072602/	S	Oral	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Subcutaneous	Unk	Not Reported
Ciclosporin	C	Unknown	Unk	Not Reported
Azathioprine	C	Unknown	Unk Unk, Qd	Not Reported
Penicillamine	C	Unknown	Unk	Not Reported
Minocycline	C	Unknown	Unk	Not Reported
Prednisolone	C	Unknown	6 Mg, Qd	Not Reported
Tocilizumab	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	6 Mg, Bid	Not Reported
Actemra	C	Unknown	Unk	Not Reported
Cyclosporine	C	Unknown	Unk	Not Reported
D-Penicillamine	C	Unknown	Unk	Not Reported
Phenylbutazone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	13059209	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015767			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown			Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported

Enbrel	S	Subcutaneous			Not Reported
Humira	S	Subcutaneous	40 Mg, Unk		Not Reported
Methotrexate	S	Unknown			Not Reported
Orencia	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Plaquenil /00072603/	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	13251533	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006675		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S				Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	Unk (Therapy Duration: 129 Unit Unspecified)		Not Reported
	Enbrel			S	Subcutaneous	1 Df, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.O.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	125 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Mefenamic Acid	C	Unknown			Not Reported
Prednisone	C	Oral	6 Mg, Qd		Not Reported
Prednisone	C	Oral	10 Mg, Qd		Not Reported
Tylenol /00020001/	C	Unknown	Unk		Not Reported
Acetaminophen	C	Unknown	Unk		Not Reported
Dequalinium Chloride	C	Unknown	Unk		Not Reported
Advil /00044201/	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	13939347	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017491		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Actemra			S	Unknown			Not Reported
	Lyrica			S	Oral	150 Mg, Bid		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Q.Wk.		Not Reported
	Tylenol /00020001/			C	Unknown	Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	13976657	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018044		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Back Disorder; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Hydroxychloroquine	S	Unknown	200 Mg, Qd	Apotex
	Leflunomide	S	Unknown	20 Mg, Qd	Apotex
	Leflunomide	S	Oral	20 Mg, 1 Every 2 Week	Apotex
	Apo-Leflunomide	S	Unknown	20 Mg, Unk	Apotex
	Apo-Leflunomide	S	Unknown	20 Mg, Qd	Apotex
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
	Anakinra	S	Subcutaneous	100 Mg, Qd	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous	40 Mg, 1 Every 2 Weeks	Not Reported
	Methotrexate	S	Oral	20 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Oral	12.5 Mg, Qd	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg, Qd	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Mg, 1 Every 4 Weeks	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Mg, Q.M.T.	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	14235971	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021661		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	1 Df, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Methotrexate Sodium	S	Unknown	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Plaquenil /00072602/	S	Unknown	Unk		Not Reported
Prednisone	C	Oral	6 Mg, Qd		Not Reported
Prednisone	C	Oral	10 Mg, Qd		Not Reported
Tylenol /00020001/	C	Unknown	Unk		Not Reported
Mefenamic Acid	C	Unknown	Unk		Not Reported
Advil /00044201/	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	14747260	EXPEDITED (15-DAY)		OT	CA-ROCHE-2105393		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Pain; Sciatica; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Caffeine;Codeine;Paracetamol	S	Unknown	Not Reported
	Tylenol No.2	S	Unknown	Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	S	Ophthalmic	Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	S	Ophthalmic	Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	S	Unknown	Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Levothyroxine	S	Unknown	Not Reported
	Levothyroxine	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Prednisone	S	Unknown	Not Reported
	Ramipril	S	Unknown	Not Reported
	Cosopt	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Codeine Phosphate	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Diphenhydramine	C		Not Reported
	Methylprednisolone	C		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported
	Tylenol	C		Not Reported
	Acetaminophen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	14815456	EXPEDITED (15-DAY)		OT	CA-ROCHE-2111505		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug	Actemra			S	Unknown			Not Reported

Ineffective; Musculoskeletal Stiffness; Pain; Pulmonary Fibrosis	Prednisone		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	Not Reported
	Enbrel		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	15268961	EXPEDITED (15-DAY)		HO	CA-ROCHE-2166736		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	15330290	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019415			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea;	Leflunomide			S	Unknown	Unk		Apotex

Oral Discomfort; Uveitis	Hydroxychloroquine		S	Unknown	Unk	Apotex
	Enbrel		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
	Methotrexate		S	Oral	Unk	Not Reported
	Methotrexate		S	Subcutaneous	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Tocilizumab		S	Unknown	Unk	Not Reported
	Xeljanz		S	Unknown	Unk	Not Reported
	Prednisone		C	Unknown	10 Mg, Unk	Not Reported
	Cimzia		C	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	15337341	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019544		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obstructive Airways Disorder; Platelet Count Decreased; Pneumonitis; Pulmonary Mass; Restrictive Pulmonary Disease	Apo-Leflunomide			S	Oral	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Enbrel			S	Unknown	50 Mg, Qd		Not Reported
	Lipitor			S	Unknown	40 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	300 Mg, Qd		Not Reported
	Spiriva			S	Unknown	2.5 Mg, Bid		Not Reported
	Zenhale			S	Unknown	200 Mg, Bid		Not Reported
	Zenhale			S	Unknown	400 Mg, Bid		Not Reported
	Zenhale			S	Unknown	200 Mg, Qd		Not Reported

	Tiotropium Bromide Monohydrate			S	Unknown	2.50 Mg, Bid				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	15342993	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176790		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Ramipril			S	Unknown			Not Reported
	Apo-Ramipril			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	15389857	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-082887		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blister; Confusional State; Contusion; Drug Ineffective; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Peripheral Swelling; Pruritus; Pyrexia; Rash; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Weight Increased	Abatacept			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Acetaminophen			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728 Milligram, Q4wk, 84 Days		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Milligram, Q4wk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Milligram 4 Every 1 Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728 Milligram 4 Every 1 Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Milligram, Qmo		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	725 Milligram		Not Reported
	Chlorhexidine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Oxycodone Hydrochloride			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Oxycodone Terephthalate			S	Unknown	Unk		Not Reported

Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Periarticular	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Sulfamethoxazole And Trimethoprim	S	Unknown	Unk	Not Reported
Chlorhexidine Gluconate	S	Unknown	Unk	Not Reported
Sulfamethoxazole	S	Unknown	Unk	Not Reported
Oxycodone And Acetaminophen	S	Unknown	Unk	Not Reported
Oxycodone	S	Unknown	Unk	Not Reported
Oxycodone Actavis	S	Unknown	Unk	Not Reported
Periogard	S	Buccal	Unk	Not Reported
Apo Acetaminophen	S	Unknown	Unk	Not Reported
Arava	C	Oral	20 Milligram, Qd	Not Reported
Arava	C	Unknown	Unk	Not Reported
Desogestrel And Ethinyl Estradiol	C	Unknown	Unk	Not Reported
Ibuprofen	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Pantoprazole Sodium	C	Unknown		Not Reported
Hydroxychloroquine Phosphate	C	Unknown	Unk	Not Reported
Prednisone	C	Oral	7.5 Milligram	Not Reported
Cetirizine Hydrochloride	C	Unknown	Unk	Not Reported
Paracetamol	C	Unknown	Unk	Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	C	Unknown	Unk	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	400 Milligram, Qd	Not Reported
Tylenol With Codeine	C	Unknown	Unk	Not Reported
Paracetamol Codeine	C	Unknown	Unk	Not Reported

	Cetrizine	C	Unknown	Unk		Not Reported
	Plaquenil S	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	16082874	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1022849		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Hospitalisation; Infection; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Acetaminophen			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown	200 Milligram Daily;		Actavis
	Leflunomide			S	Unknown	200 Milligram Daily;		Barr
	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Apo-Acetaminophen Tab 325mg	S	Unknown		Not Reported
Apo-Acetaminophen Tab 325mg	S			Not Reported
Tylenol	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Acetaminophen /Diphenhydramine Hydrochloride	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram Daily;	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram Daily;	Not Reported
Acetaminophen/Codeine Phosphate	C	Unknown		Not Reported
Meloxicam	C	Unknown		Not Reported
Synthroid	C	Unknown		Not Reported
Synthroid	C			Not Reported
Xeljanz	C	Unknown		Not Reported
Celebrex	C	Oral	400 Milligram Daily;	Not Reported
Hydromorphone Hcl	C	Unknown		Not Reported
Celecoxib	C	Unknown		Not Reported
Methotrexate	C	Unknown	25 Milligram Daily;	Not Reported
Methotrexate	C	Unknown		Not Reported
Tylenol W/Codeine No.3	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	16119797	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-027001		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Drug Ineffective; Drug Intolerance; Dyspnoea; Eating Disorder; Eye Disorder; Fatigue; Infection; Intraocular Pressure Increased; Joint Swelling; Nausea; Ocular Hypertension; Ovarian Neoplasm; Pain In Extremity; Pneumonia; Rash; Unevaluable Event; Weight Decreased	Orencia	S	Unknown	Therapy Duration 10.0 Month(S)	Bristol Myers Squibb
	Arava	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Therapy Duration 30 Days	Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Unknown	Therapy Duration 6.0 Years	Not Reported
	Leflunomide	S	Unknown	62.0 Days	Not Reported
	Methotrexate	S	Unknown	123 Days	Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	16641652	EXPEDITED (15-DAY)		OT	CA-ROCHE-2361846			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Acetaminophen;Codeine Phosphate			C	Unknown			Not Reported

	Meloxicam	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17250187	EXPEDITED (15-DAY)		OT	CA-ROCHE-2513966		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Joint Swelling; Pneumonia; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syring, Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Cefalexin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17454345	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007815		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma	Hydroxychloroquine	S	Unknown	Unk		Apotex
	Apo-Leflunomide	S	Unknown	Unk		Apotex
	Enbrel	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk		Not Reported
	Desoximetasone	C	Unknown	10 Mg, Qd		Not Reported
	Diclofenac	C	Unknown	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17595157	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020012294		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis;	Cimzia			S	Subcutaneous	400 Milligram		Ucb
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Ucb
	Cetirizine Hydrochloride			S				Ucb
	Stelara			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S				Not Reported
	Cortisone Acetate			S		25 Milligram		Not Reported
	Desoximetasone			S	Oral	And Oral		Not Reported
	Diclofenac			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Folic Acid	S		5 Milligram	Not Reported
	Folic Acid	S	Oral	25 Milligram	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	4 Milligram	Ucb
	Humira	S		40 Milligram	Ucb
	Leflunomide	S		Unk	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S		400 Milligram, Once Daily (Qd)	Not Reported
	Pseudoephedrine Hcl	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S			Not Reported
	Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Once Daily (Qd)	Not Reported
	Sulfathalidine	S		Unk	Not Reported
	Topicort [Desoximetasone]	S	Subcutaneous	Unk	Not Reported
	Topicort [Desoximetasone]	S	Topical	Unk	Not Reported
	Xeljanz	S		5 Milligram, 2x/Day (Bid)	Not Reported
	Xeljanz	S		5 Milligram, 2x/Day (Bid)	Not Reported
	Xeljanz	S		5 Milligram, 2x/Day (Bid)	Not Reported
	Xeljanz	S		5 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Hydroxyquine	S		Unk	Not Reported

	Apo-Prednisone	S		40 Milligram	Not Reported
	Apo-Prednisone	S			Not Reported
	Arava	S		Unk	Not Reported
	Salazopyrin	C			Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	S	Subcutaneous	25 Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17662224	EXPEDITED (15-DAY)		DE, HO, OT	SK-GLAXOSMITHKLINE-SK2020061907		57 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Bulbar Palsy; Cardiac Arrest; Cerebral Infarction; Dizziness; Hypotension; Intentional Product Use Issue; Jc Virus Infection; Mental Impairment; Off Label Use; Pneumonia; Progressive Multifocal Leukoencephalopathy; Respiratory Failure; Speech Disorder; Tremor	Belimumab			S	Unknown	Unk		Glaxosmithkline
	Azathioprine			S	Unknown	Unk		Glaxosmithkline
	Cyclosporine A			S	Unknown	Unk		Glaxosmithkline
	Methotrexate			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17674805	EXPEDITED (15-DAY)		DE, HO, OT	SK-ORION CORPORATION ORION PHARMA-20_00008910		57 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Bulbar Palsy; Cardiac Arrest; Cerebral Infarction; Dizziness; Hypotension; Jc Virus Infection; Mental	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

Impairment; Pneumonia; Product Use In Unapproved Indication; Progressive Multifocal Leukoencephalopathy; Respiratory Failure; Speech Disorder; Tremor	Azathioprine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Cyclosporine A	S	Unknown	Not Reported
	Belimumab	S	Unknown	Not Reported
	Cyclophosphamide	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17684289	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1038428		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Off Label Use; Pyrexia; Systemic Lupus Erythematosus; Therapy Non-Responder	Prednisone			S	Unknown	Unk (50 Mg Qd, Tapering Dose)		Not Reported
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk (25 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S	Unknown	12.5 Mg Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd		Not Reported
	Prednisone			S	Unknown	15 Mg Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	Unk Unk (10 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S	Unknown	Unk Unk (7.5 Mg Qd, Dose Tapering)		Not Reported
	Tacrolimus			S		1 Dosage Form, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Mylan
	Envarsus			S	Unknown	Unk, Qd		Mylan
	Belimumab			S	Unknown	Unk		Mylan
	Belimumab			S	Unknown	Unk		Mylan
	Belimumab			S	Unknown	Unk		Mylan

	Belimumab	S	Unknown	Unk	Mylan
	Mycophenolate Mofetil	S	Unknown	1 Dosage Form, Qd	Mylan
	Rituximab	C		Unk	Mylan
	Methylprednisolone	C		Unk (Pulses)	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17696993	EXPEDITED (15-DAY)		HO, OT	BR-ADVANZ PHARMA-202004003349			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Off Label Use; Psychotic Disorder	Hydroxychloroquine			S		200 Mg, Bid (Q12h Nasoenteric Probe), Coated Tablet		Concordia
	Hydroxychloroquine			S		200 Mg, Bid (Q12h Nasoenteric Probe), Coated Tablet		Concordia
	Azithromycin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Metamizole Sodium			C		Unk		Not Reported
	Sodium Heparin			C		Unk		Not Reported
	Methylprednisolone Sodium Succinate			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Methadone Hydrochloride			C		Unk		Not Reported
	Piperacilina+Tazobactam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17696996	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202004003506			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Off Label Use	Hydroxychloroquine			S	Oral	600 Mg, Qd		Concordia
	Hydroxychloroquine			S	Oral	400 Mg, Qd (Film-Coated Tablet)		Concordia

	Hydroxychloroquine	S	Oral	400 Mg, Qd	Concordia
	Fludrocortisone	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17722247	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-032972			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulphathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Simponi		S	Subcutaneous		Not Reported
	Reactine [Cetirizine Hydrochloride]		S	Unknown		Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17737409	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589933		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rosuvastatin Calcium			C	Oral			Not Reported
	Nitroglycerin			C				Not Reported
	Gabapentin			C	Oral			Not Reported
	Asa			C	Unknown			Not Reported
	Clonazepam			C	Oral			Not Reported
	Desipramine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739425	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-02		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract;	Mobicox			S	Unknown			Boehringer Ingelheim

Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Actemra	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Meloxicam	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Depo-Medrol	C	Intra-articular	Dosage Form: Suspension Intra-Articular	Not Reported
	Diclofenac	C	Unknown		Not Reported
	Pantoprazole Magnesium	C	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739591	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-021847		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Cardio-Respiratory Arrest	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram,1 Total		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Two Times A Day		Not Reported
	Kaletra			S				Not Reported
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739633	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592035			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739649	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591873			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Topicort [Desoximetasone]	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739663	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-02		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis;	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Form Of Admin: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depomedrol			C	Intramuscular	Form Of Admin: Suspension For Infusion		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported

Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Plaquenil [Hydroxychloroquine Phosphate]	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739747	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245893		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Loss Of Consciousness; Malaise; Ventricular Extrasystoles	Azithromycin			S	Oral	Unk		Sun
	Plaquenil			S	Oral	Unk		Not Reported
	Lovenox			C	Oral	Unk		Not Reported
	Paracetamol			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739833	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1945		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Disorder; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Flexeril			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Visanne			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739836	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Gait Disturbance; Joint Swelling; Muscular Weakness; Nerve Injury; Pain; Paraesthesia; Rheumatoid Arthritis; Sciatica; Spinal Stenosis; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	Q Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Q Unk		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actonel Xr			C	Unknown	Every Unspecified Unit (Q)		Not Reported
	Baclofen			C	Unknown	Every Night (Hs)		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Vitamin D			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739897	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590110		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Intolerance; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Actemra			S	Subcutaneous	8.0 Months		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Esomeprazole Sodium			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

	Gold	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Nicotinamide	S	Unknown	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Sarilumab	S	Subcutaneous	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Thiamine Hydrochloride	S	Unknown	Not Reported
	Esomeprazole Magnesium Trihydrate	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739900	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245906		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Sun
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Other	400 Mg Dia ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740011	NON-EXPEDITED			IN-LUPIN PHARMACEUTICALS INC.-2020-00693		31 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy	Hydroxychloroquine			S	Unknown	5 Milligram/Kilogram		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740014	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2020-01594		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740015	NON-EXPEDITED		LT, OT	US-LUPIN PHARMACEUTICALS INC.-2020-01647		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy	Hydroxychloroquine			S	Unknown	Unk		Lupin
	R Chop			C	Unknown	Unk		Not Reported
	Doxorubicin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740016	NON-EXPEDITED			GB-LUPIN PHARMACEUTICALS INC.-2020-00911		83 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Nausea	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Methotrexate			C	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk Unk, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740017	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2020-01472			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740069	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004004409			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hand Fracture; Hip Fracture; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	200 Mg, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740109	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201812000036			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Hypersensitivity; Drug Ineffective; Hypersensitivity; Insomnia; Loss Of Personal Independence In Daily Activities; Pain; Rheumatoid Arthritis; Stress At Work; Swelling	Hydroxychloroquine			S	Unknown	Unk, Tablet		Concordia
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			C				Not Reported
	Acetaminophen And Codeine Phosphate			C		Unk		Not Reported
	Cimzia			C		Unk		Not Reported
	Humira			C		Unk		Not Reported
	Orencia			C		Unk		Not Reported
	Actemra			C		Unk		Not Reported
	Simponi			C		Unk		Not Reported
	Lyrica			C		Unk		Not Reported
	Arthrotec			C		Unk		Not Reported
	Tylenol			C		Unk		Not Reported
	Rabeprazole			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740123	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590820			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740137	EXPEDITED (15-DAY)		HO, OT	DE-TEVA-2020-DE-1229760		71 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Off Label Use	Hydroxychloroquine			S	Oral	1200 Milligram Daily;		Teva
	Hydroxychloroquine			S		200 Milligram Daily;		Teva
	Hydroxychloroquine			S				Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740608	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012639			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus	Diclofenac			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported

Erythematosus; Wound	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740669	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245901		63 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Sun
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg ; In Total		Not Reported
	Dolquine 200 Mg Comprimidos			S	Oral	400 Mg Dia		Not Reported

Recubiertos, 30 Comprimidos

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740724	EXPEDITED (15-DAY)		DE, OT	ES-GLAXOSMITHKLINE-ES2020073213		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Long Qt Syndrome; Sudden Death	Metoclopramide			S	Intravenous (not otherwise specified)	10 Mg, Tid		Glaxosmithkline
	Salbutamol			S	Respiratory (inhalation)	0.1 Mg, Qid		Glaxosmithkline
	Azithromycin			S	Oral	500 Mg, Qd		Glaxosmithkline
	Dolquine			S	Oral	400 Mg		Not Reported
	Propofol			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enoxaparin Sodium			C	Subcutaneous	Unk		Not Reported
	Cefotaxim			C	Intravenous drip	4 G, Bid		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	600 Mg, Qd		Not Reported
	Midazolam			C	Intravenous drip	100 Mg, Qd		Not Reported
	Ipratropii Bromidum			C	Respiratory (inhalation)	20 ?G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740754	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-GSH201907-001630			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Drug Eruption; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia; Epstein-Barr Virus Infection Reactivation; Face Oedema; Leukocytosis;	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Methylprednisolone			S	Unknown	60 Mg, Qid		Not Reported
	Methylprednisolone			S	Unknown	80 Mg, Bid		Not Reported
	Methylprednisolone			S	Oral	Unkunknown (Tapered To Oral Methylprednisolone)		Not Reported

Oedema Peripheral;
Pyrexia; Rash; Rash;
Rash; Rash Pruritic;
Rebound Effect;
Transaminases Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740767	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591294			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C				Not Reported
	Caffeine			C				Not Reported
	Codeine Phosphate			C				Not Reported
	Meprobamate			C				Not Reported
	Dorzolamide Hydrochloride			C				Not Reported
	Timolol Maleate			C				Not Reported
	Folic Acid			C				Not Reported
	Levothyroxine			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported
	Ramipril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740826	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010325			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Colitis Microscopic; Gastrointestinal Disorder; Rash	Leflunomide	S	Unknown	20.0 Mg, Unk	Apotex
	Plaquenil /00072602/	S	Unknown		Not Reported
	Methotrexate	C	Subcutaneous	25 Mg, Q.Wk.	Not Reported
	Sulfasalazine	C	Unknown	2.0 G, Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Q.12h	Not Reported
	Venlafaxine Hydrochloride	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740834	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591475			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740837	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588677		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Amyotrophic Lateral Sclerosis; Contraindicated Product Administered; Multiple System Atrophy	Actemra		S	Intravenous (not otherwise specified)	Duration 7 Years	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Duration 579	Not Reported
	Xeljanz		S	Oral		Not Reported
	Xeljanz		S	Intravenous (not otherwise specified)		Not Reported
	Remicade		S	Unknown	Cyclical Duration 2 Years	Not Reported
	Orencia		S	Unknown		Not Reported
	Methotrexate		S	Oral		Not Reported
	Methotrexate		S	Oral	1 In1 Week	Not Reported
	Methotrexate		S	Subcutaneous	1 In1 Week	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Humira		S	Subcutaneous	Duration:7.0 Months	Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Prednisone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740840	EXPEDITED (15-DAY)		OT	CA-SA-2020SA114283			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus	Desoximetasone			S	Oral			Sanofi
	Leflunomide			S	Oral			Sanofi
	Cetirizine Hydrochloride			S				Not Reported
	Folic Acid			S				Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S				Sanofi
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S		400 Ml, Qd		Sanofi
	Prednisone			S				Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported

Erythematosus; Wound	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Tocilizumab	S		Not Reported
	Tofacitinib Citrate	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740849	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590808		33 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Seborrhoeic Dermatitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740856	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591172		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Neoral	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17741402	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591623			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Hip	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cimzia		S	Subcutaneous		Not Reported
	Diclofenac Sodium		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Folic Acid		S	Unknown		Not Reported
	Fosamax		S	Oral		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Oral		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution For Infusion	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17741412	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591821		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Cough; Drug Ineffective; Headache; Rheumatoid Arthritis; Treatment Failure; Viral Infection	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Orencia	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17741579	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020171234		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Zithromax			S	Oral	Unk		Pfizer
	Hydroxyzine Arrow			S	Oral	25 Mg, Single		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Other	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17741587	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020171158		41 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Chest Discomfort; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17741728	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-035310			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Oral	200 Milligram, Bid		Not Reported

	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17741744	EXPEDITED (15-DAY)		HO	CA-ROCHE-2589836		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Blood Glucose Abnormal; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Secretion Discharge; Spinal Operation; Sputum Discoloured; Therapeutic Product Effect Decreased; Thrombosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Warfarin	S	Unknown	Not Reported
	Warfarin Sodium	S	Unknown	Not Reported
	Warfarin Sodium	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17741774	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591992			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Leflunomide			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17741875	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590815			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

Mobicox	S	Oral		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Meloxicam	S	Oral		Not Reported
Sulfasalazine	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17741908	EXPEDITED (15-DAY)		DS	CA-ROCHE-2590957		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Headache; Impaired Work Ability; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Peripheral Swelling; Skin Mass	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17742198	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1229970		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Flushing; Heart Rate Decreased; Herpes Zoster; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Naproxen			S	Unknown			Teva
	Anakinra			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C				Not Reported
	Diphenhydramine Hydrochloride			C				Not Reported
	Ferrous Gluconate			C				Not Reported
	Folic Acid			C				Not Reported
	Lasix [Furosemide]			C				Not Reported
	Methylprednisolone			C				Not Reported
	Naprosyn [Naproxen]			C				Not Reported
	Oxycontin			C				Not Reported
	Oxyneo			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17742199	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1229977		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Naproxen	C	Unknown	500 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17742242	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230038			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuropathy Peripheral	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Codeine Phosphate			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Azathioprine Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17742305	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230007		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling;	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Simponi	S	Unknown	Not Reported
	Arthrotec	C		Not Reported
	Azathioprine	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17742309	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230224			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Other			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17742317	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230103			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported
	Desoximetasone			C	Oral			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Ml Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17742319	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1229996		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Drug	Leflunomide			S	Oral			Barr

Hypersensitivity; Drug Ineffective; Infection; Limb Discomfort; Rash; Rheumatoid Arthritis	Cefazolin	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Barr
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Arava	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Viread	C	Unknown		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17742383	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591127			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Aluminum Acetate			C				Not Reported
	Atacand			C	Unknown			Not Reported

	Benzethonium Chloride	C		Not Reported
	Neurontin	C	Unknown	Not Reported
	Ergocalciferol	C		Not Reported
	Folic Acid	C		Not Reported
	Hydrodiuril	C		Not Reported
	Premarin	C		Not Reported
	Tylenol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17742438	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230239			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Blister; Drug Ineffective; Feeling Abnormal; Gastrointestinal Disorder; Hepatic Enzyme Abnormal; Inappropriate Schedule Of Product Administration; Mouth Haemorrhage; Mouth Ulceration; Musculoskeletal Discomfort; Nausea; Psoriatic Arthropathy; Pyrexia; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Arthrotec			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Lipitor			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Dovobet			C	Topical			Not Reported
	Flovent			C	Respiratory (inhalation)			Not Reported
	Folic Acid			C	Oral			Not Reported
	Multi Vitamin			C	Oral			Not Reported
	Omeprazole			C	Oral			Not Reported
	Ventolin			C	Respiratory			Not Reported

				(inhalation)	
	Vitamin D2		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17742609	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1043063			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Heart Rate Abnormal; Premature Baby	Prednisone			S	Transplacental	Maternal Dose: 10 Mg, Qd		Not Reported
	Kiovig			S	Transplacental	Unk		Mylan
	Hydroxychloroquine			S	Transplacental	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17742756	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230080		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Parenteral			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

Orencia	S	Unknown			Not Reported
Tocilizumab	C	Unknown			Not Reported
Penicillamine	C	Unknown			Not Reported
Prednisone	C	Unknown	12 Milligram Daily;		Not Reported
Azathioprine	C	Unknown			Not Reported
Ciclosporin	C	Unknown			Not Reported
Minocycline	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17742810	EXPEDITED (15-DAY)		LT	CA-TEVA-2020-CA-1230043		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis;	Leflunomide			S	Unknown			Barr
	Leflunomide			S				Barr
	Methotrexate Sodium			S	Unknown			Barr
	Methotrexate Sodium			S	Unknown			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Minocycline Hydrochloride			S	Unknown			Actavis
	Oxycodone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported

Terminal State; Thrombosis; Urticaria	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S		Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S		Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]	S		Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Xeljanz	S	Oral	Not Reported
	Gold	S	Unknown	Not Reported
	Kineret	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17742993	EXPEDITED (15-DAY)		HO	SE-MYLANLABS-2020M1043195		16 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Fatigue; Intentional Overdose; Intentional Self-Injury; Somnolence; Tachycardia	Sertraline			S	Oral	750 Milligram		Not Reported
	Prednisolone			S	Oral	10-15st.		Not Reported
	Plaquenil /00072603/			S	Oral	10-15 St.		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17743520	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1230201			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Thrombosis; Urticaria	Leflunomide			S	Unknown			Barr
	Leflunomide			S				Barr
	Oxycodone			S	Unknown			Actavis
	Minocycline Hydrochloride			S	Unknown			Actavis
	Minocycline Hydrochloride			S	Unknown			Actavis
	Methotrexate Sodium			S	Unknown			Barr
	Methotrexate Sodium			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported
	Gold			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Marijuana			S	Unknown			Not Reported

Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S			Not Reported
Plaquenil[Hydroxychloroquine Sulfate]	S	Oral		Not Reported
Plaquenil[Hydroxychloroquine Sulfate]	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S			Not Reported
Rituximab	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Sodium Aurothiomalate	S			Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S			Not Reported
Xeljanz	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17743532	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230195		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram Daily;		Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17743534	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1230217		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Alendronate Sodium			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Enbrel	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Myochrysine	S	Parenteral	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Ciclosporin	C	Oral	Not Reported
Prednisone	C		Not Reported
Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17743538	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230200		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Leflunomide			S	Oral			Barr
	Methotrexate			S	Parenteral			Barr
	Adalimumab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Infliximab	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Unknown	Not Reported
Rituximab	S	Subcutaneous	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Azathioprine	C	Unknown	Not Reported
Ciclosporin	C	Unknown	Not Reported
Minocycline	C	Unknown	Not Reported
Penicillamine	C	Unknown	Not Reported
Prednisolone	C	Unknown	Not Reported
Tocilizumab	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17743552	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230190		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Leflunomide			S	Oral	5 Mg		Barr
	Methotrexate			S	Unknown	5 Mg		Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Xeljanz		S	Oral	10 Milligram Daily;	Not Reported
	Prednisone		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17743595	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230196		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Factor Positive	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Azathioprine			C	Unknown			Not Reported
	Arthrotec			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Gold			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745001	DIRECT	Y	DE			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Hydroxychloroquine			S	Oral			Actavis
	Actemra	Y		S	Intravenous bolus	Other Frequency:X1;		Genentech

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745146	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230094		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Pantoprazole			C				Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Tenofovir			C	Unknown			Not Reported
	Tenofovir Disoproxil			C	Unknown			Not Reported
	Tenofovir Disoproxil Fumarate			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Zopiclone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745147	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230084			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspnoea; Hypertension; Neoplasm Malignant	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745151	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230198		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma	Leflunomide			S	Oral			Barr
	Leflunomide			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown	10 Milligram Daily;		Not Reported
	Diclofenac			C	Unknown	100 Milligram Daily;		Not Reported
	Methotrexate			C	Unknown			Not Reported

Voltaren [Diclofenac]	C	Unknown	100 Milligram Daily;		Not Reported
Xeljanz	C	Unknown			Not Reported
Zostavax	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745152	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230102		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Infection; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Diclofenac Sodium/Misoprostol			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported

	Arthrotec	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported
	Imuran [Azathioprine]	C	Unknown	Not Reported
	Vitamin D [Colecalciferol]	C	Unknown	Not Reported
	Vitamin D3	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745153	EXPEDITED (15-DAY)		DE, LT	CA-TEVA-2020-CA-1230049		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Methotrexate Sodium			S	Unknown			Barr
	Minocycline			S	Unknown			Actavis
	Minocycline Hydrochloride			S	Unknown			Actavis
	Oxycodone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported
	Gold			S				Not Reported
	Humira			S	Subcutaneous			Not Reported

Humira	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Marijuana	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
Remicade	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Sodium Aurothiomalate	S		Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Ilaris	C	Unknown	Not Reported
Ilaris	C	Subcutaneous	Not Reported
Kineret	C	Unknown	Not Reported
Lyrica	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745154	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230199			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Infection; Lung Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745155	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1230197		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash	Leflunomide			S	Oral			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Codeine Sulfate			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Actavis
	Alendronate Sodium			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Myochrysine	S	Parenteral		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Ciclosporin	C	Unknown	150 Milligram Daily;	Not Reported
	Prednisone	C	Unknown	10 Milligram Daily;	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745157	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020017803			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Cimzia			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Apo-Leflunomide			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Methotrexate	S	Oral		Not Reported
	Orencia	S		Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S		Unk	Not Reported
	Tocilizumab	S		Unk	Not Reported
	Xeljanz	S			Not Reported
	Rabeprazole Sodium	C	Oral	20 Milligram, Once Daily (Qd)	Not Reported
	Tofacitinib	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745174	EXPEDITED (15-DAY)		HO	ES-ABBVIE-20K-144-3388205-00		68 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Renal Impairment	Kaletra 200/50			S	Oral			Not Reported
	Ciclosporina			S	Oral			Not Reported
	Dolquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745245	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034937		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass; Nodule; Rheumatoid	Orencia			S	Unknown			Bristol Myers Squibb
	Actonel			S	Oral	35 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Arthritis; Stress; Therapeutic Product Effect Decreased	Leflunomide		S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate		S	Oral	22.5 Milligram, Qwk	Not Reported
	Novo-Rythro		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Bupropion		C	Unknown		Not Reported
	Cannabis Sativa		C	Unknown		Not Reported
	Celebrex		C	Unknown	200 Milligram, Bid	Not Reported
	Ergocalciferol		C	Unknown	Unk, Qd	Not Reported
	Hydroxychloroquine		C	Oral	400 Milligram, Qd	Not Reported
	Wellbutrin		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745333	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-022011		56 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hypoacusis	Azithromycin			S	Oral	500 Milligram, Once A Day, (500 Mg Dia)		Aurobindo
	Hidroxicloroquina			S	Oral	400 Milligram, Once A Day, (400 Mg Dia)		Not Reported
	Hidroxicloroquina			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745350	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232076		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Risedronate Sodium			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	C		300 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745363	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232129		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Product Use Issue; Rheumatoid Arthritis	Leflunomide			S	Unknown	1 Dosage Forms Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Risedronate Sodium			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	1 Dosage Forms Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	12326256	EXPEDITED (15-DAY)		OT	CA-ROCHE-1750136		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Anti-Cyclic Citrullinated Peptide Antibody Positive;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral	Therapy Duration: 365		Not Reported

Arthralgia; Arthropathy; Bone Cyst; Bone Erosion; C-Reactive Protein Abnormal; Diabetes Mellitus; Drug Ineffective; Hepatic Steatosis; Hypertension; Joint Ankylosis; Joint Swelling; Liver Disorder; Musculoskeletal Stiffness; Osteolysis; Pain; Red Blood Cell Sedimentation Rate Abnormal; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Upper Respiratory Tract Infection				Nos	
	Arava	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Therapy Duration: 880 Days	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Oral	Therapy Duration: 20 Years	Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Methotrexate Sodium	S	Oral	12.0 Months	Not Reported
	Methotrexate Sodium	S	Oral	20.0 Years	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Subcutaneous		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Cortisone	C	Unknown		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Infliximab	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	12590542	EXPEDITED (15-DAY)		OT	CA-ROCHE-1627133		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Actemra		S	Subcutaneous		Not Reported
	Actemra		S	Intravenous (not otherwise specified)		Not Reported
	Cimzia		S	Unknown		Not Reported
	Folic Acid		S	Unknown		Not Reported
	Humira		S	Unknown		Not Reported
	Arava		S	Oral	Frequency: Every 1 Day	Not Reported
	Methotrexate Sodium		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Every Day Besides Sunday	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported
	Xeljanz		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	13067385	EXPEDITED (15-DAY)		OT	CA-ROCHE-1871931			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	13187329	EXPEDITED (15-DAY)		OT	CA-ROCHE-1886111		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Back Pain; Blood Pressure Increased; Contusion; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage; Hypersensitivity; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Osteoarthritis; Osteoporosis; Pain; Pruritus; Rash; Spinal Disorder; Spinal Operation; Swelling; Therapy Non-Responder	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	13519755	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038176		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb

Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Paracetamol	S	Unknown	Unk	Bristol Myers Squibb
	Actemra	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Arava	S	Oral	20 Milligram	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Unknown	25 Milligram	Not Reported
	Desoximetasone	S	Cutaneous	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	500 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Unknown	500 Milligram	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Folic Acid	S	Oral	1 Milligram	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Oral	5 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported

Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	4 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
Methotrexate	S	Oral	25 Milligram, Qd	Not Reported
Methotrexate	S	Oral	Unk, Qd	Not Reported
Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
Prednisone	S	Unknown	1 Mg, Unk	Not Reported
Prednisone	S	Unknown	40 Milligram	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Cetirizine Hydrochloride	S	Oral	10 Milligram	Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	20 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1 G, Qd	Not Reported
Sulfasalazine	S	Oral	1 G, Bid	Not Reported
Sulfasalazine	S	Unknown	1 G, Bid	Not Reported

Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1000 Milligram, Bid	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Urethral	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	40 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram, Qd	Not Reported
Apo-Prednisone	S	Unknown	5 Mg, Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Hydroxychloroquine Phosphate	S	Oral	400 Milligram, Qd	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	25 Milligram	Not Reported
Apo-Folic Acid	S	Unknown	15 Milligram	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine	S	Unknown	25 Milligram	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	50 Milligram	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Hydrocortisone Acetate	S	Unknown	Unk	Not Reported

Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
Cortisone Acetate	S	Topical	25 Milligram	Not Reported
Cortisone Acetate	S	Unknown	Unk	Not Reported
Cortisone Acetate	S	Oral	Unk	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Methotrexate Sodium	S	Subcutaneous	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Subcutaneous	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Other	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Oral	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	40 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	40 Milligram, Qd	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	10 Milligram	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	20 Milligram	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported

Etanercept	S	Subcutaneous	Unk		Not Reported
Adalimumab	S	Subcutaneous	Unk		Not Reported
Acetaminophen	S	Unknown	Unk		Not Reported
Tofacitinib Citrate	C	Unknown	Unk		Not Reported
Salazopyrin	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Leflunomide	C	Oral	Unk		Not Reported
Atasol [Paracetamol]	C	Unknown	Unk		Not Reported
Ibuprofen	C	Unknown			Not Reported
Lisinopril	C	Unknown			Not Reported
Prednisolone	C	Unknown	Unk		Not Reported
Vitamin D3	C	Unknown			Not Reported
Diclofenac	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	13939230	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017490		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain Upper; Aggression; Alopecia; Anxiety; Arthralgia; Asthenia; Blood Creatinine Increased; Cough; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspnoea; Increased Upper Airway Secretion; Insomnia; Joint Swelling; Lung Disorder; Malaise; Off Label Use; Peripheral Swelling; Productive Cough; Retinopathy; Secretion Discharge; Sinus Disorder;	Apo-Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Unk		Not Reported
	Prolia			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Cymbalta			C	Unknown	Unk		Not Reported

Sinusitis; Synovitis; Tachyphylaxis; Urinary Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	13958227	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017824		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Pain	Hydroxychloroquine			S	Oral	Unk, Qd		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Actemra			S	Unknown			Not Reported
	Lyrica			S	Oral	Unk, Bid		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Q.Wk.		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Tylenol /00020001/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	13967555	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017891		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

Methotrexate	S	Unknown	20 Mg, Unk		Not Reported
Orencia	S	Unknown	750 Mg, Unk		Not Reported
Orencia	S	Unknown	750 Mg, Unk		Not Reported
Remicade	S	Unknown	Unk		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported
Meloxicam	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	14241987	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021746		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Feeding Disorder; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Varenicline Tartrate			S	Oral	1 Df, Qd		Not Reported
	Varenicline Tartrate			S	Oral	Unk Unk, Q.Wk.		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Valtrex			C	Oral	1000 Mg, Bid		Not Reported
	Valtrex			C				Not Reported
	Rosuvastatin Calcium			C	Oral	Unk Unk, Qd (Once Every		Not Reported

				24 Hours)	
	Esomeprazole Magnesium W/Naproxen	C	Oral	500 Mg, Bid	Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	C	Oral	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Oral	500 Mg, Bid	Not Reported
	Naproxen	C	Oral	500 Mg, Bid	Not Reported
	Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	14746347	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009094		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Tremor	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S				Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Orencia			S	Unknown	40 Mg/Kg, Q.O.Wk.		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Oral	2.5 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	15 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	1 Df, Q.Wk.		Not Reported
	Methotrexate			S	Oral	10 Mg, Q.Wk.		Not Reported

Adalimumab	S	Unknown	Unk	Not Reported
Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
Pantoprazole Magnesium	C	Oral	40 Mg, Qd	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Oral	300 Mg, Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	300.0 Mg, Unk	Not Reported
Xeljanz	C	Unknown		Not Reported
Zopiclone	C	Unknown	7.5 Mg, Qd	Not Reported
Folic Acid	C	Oral	2.5 Mg, Qd	Not Reported
Folic Acid	C			Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	14815367	EXPEDITED (15-DAY)		OT	CA-ROCHE-1712238		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Joint Arthroplasty; Knee Arthroplasty; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis;	Actemra			S	Unknown	Therapy Duration: 2 Years		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 2.0 Year(S)		Not Reported
	Anakinra			S	Subcutaneous	Therapy Duration: 2 Years		Not Reported
	Anakinra			S	Subcutaneous	Therapy Duration: 3 Years		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 4 Months		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 2 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 3 Months		Not Reported
	Humira			S	Subcutaneous			Not Reported

Vasculitic Rash	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	Therapy Duration: 2 Months	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Oral	Duration: 8.0 Months	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Xeljanz	C	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Methotrexate Sodium	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	14917304	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-093137		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition	Orencia			S	Unknown			Bristol Myers Squibb
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

Aggravated; Deformity; Diarrhoea; Disease Progression; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Humira		S	Subcutaneous	Unk	Not Reported
	Celebrex		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	500 Milligram	Not Reported
	Apo-Warfarin		S	Unknown	Unk	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Enbrel		S	Unknown		Not Reported
	Anakinra		S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]		S	Unknown		Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Warfarin		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	15050148	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021593		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Apotex
	Leflunomide			S	Unknown	20 Mg, Every 1 Day		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, Bid		Not Reported
	Enbrel			S	Unknown	25 Mg, 2 Every 1 Weeks		Not Reported
	Enbrel			S	Unknown	25 Mg, 1 Every 2 Weeks		Not Reported
	Humira			S	Unknown	40 Mg, 1 Every 2 Weeks For 4 Months And 6 Months		Not Reported
	Humira			S	Unknown	40 Mg, Cyclical		Not Reported
	Humira			S	Unknown	40 Mg, Q.O.Wk.		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Q.Wk. (Therapy Duration: 790 Unit		Not Reported

				Unspecified)	
	Plaquenil /00072602/	S	Unknown	200 Mg, Bid	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, 1 Every 6 Weeks	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	20 Mg, Unk (Therapy Duration: 790 Unit Unspecified)	Not Reported
	Methotrexate	S	Unknown	15 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	200 Mg, Q.Wk.	Not Reported
	Wellbutrin	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	1 G, Bid	Not Reported
	Sulfasalazine	C			Not Reported
	Xeljanz	C	Unknown		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	15076484	EXPEDITED (15-DAY)		CA, OT	CA-APOTEX-2018AP015974			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Adalimumab			S	Subcutaneous	40 Mg, Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Unk 1 Every 14 Days		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Unk 1 Every 10 Days		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported

	Humira	S	Subcutaneous	40 Mg, Unk 1 Every 10 Days	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk 1 Every 14 Days	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Tofacitinib	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Kevzara	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Rabeprazole Sodium	C	Oral	20 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	15331158	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176740		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Contraindicated Product Administered; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Haemorrhage; Gait Disturbance; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Rash; Syncope; Urticaria	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prevacid	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	15386769	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-20713376		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Dermatomyositis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Intentional Product Use Issue; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Pain; Thrombosis; Uterine Disorder; Weight Increased	Warfarin Sodium			S	Unknown	Unk		Bristol Myers Squibb
	Metformin Hydrochloride			S	Unknown	Unk		Bristol Myers Squibb
	Metformin Hydrochloride			S	Unknown			Bristol Myers Squibb
	Cymbalta			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

	Imuran [Azathioprine]	C	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported
	Xarelto	C	Unknown	Unk		Not Reported
	Azathioprine Sodium	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	15412303	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186769			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Feeding Disorder; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varenicline Tartrate			S	Oral			Not Reported
	Varenicline Tartrate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Unknown			Not Reported
	Tofacitinib Citrate			C	Unknown			Not Reported
	Valtrex			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	15450369	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190759			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Folic Acid			C	Unknown	Dosage Forms : 1.0		Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	15619576	EXPEDITED (15-DAY)		HO, OT	GR-ACCORD-091884		56 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Drug Ineffective; Dyspnoea; Leukopenia; Microangiopathic Haemolytic Anaemia; Orthopnoea; Product Use In Unapproved Indication; Raynaud'S Phenomenon; Renal Impairment; Scleroderma Renal Crisis;	Methotrexate			S	Unknown	15 Mg, Qw		Accord
	Citalopram			S	Unknown			Not Reported
	Captopril			S				Not Reported
	Alprazolam			S	Unknown			Not Reported
	Folic Acid			S	Unknown	5 Mg, Qw		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Hydroxychloroquine/Hydroxychloroquine Phosphate/Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported

Scleroedema; Therapy Non-Responder; Thrombocytopenia; Weight Decreased	Sulfate					Not Reported
	Adalimumab	S				Not Reported
	Prednisolone	S	Unknown	10 Mg, Qd		Not Reported
	Valsartan	C				Not Reported
	Prednisolone	S	Unknown	7.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	16359788	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2019-03160		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myopathy Toxic	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Lupin
	Losartan			C	Unknown	100 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	16691209	EXPEDITED (15-DAY)		OT	CA-SA-2019SA208308			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Leflunomide			S	Unknown	10 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Unk		Sanofi
	Rituximab			S	Unknown	Unk Unk, Unk		Not Reported
	Remicade			S	Unknown	Unk Unk, Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Simponi			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	16696905	EXPEDITED (15-DAY)		HO, LT, OT	CA-SA-2019SA208335		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Leflunomide			S	Oral	Unk Unk, Unk		Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Leflunomide			S	Oral	Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S		Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S		Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S		Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S		Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S		Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S	Oral	Unk Unk, Unk		Sanofi
	Methotrexate			S		Unk Unk, Unk		Not Reported
	Methotrexate			S		Unk Unk, Unk		Not Reported
	Methotrexate			S		Unk Unk, Unk		Not Reported
	Methotrexate			S	Intra-arterial	Unk Unk, Unk		Not Reported
	Plaquenil			S		Unk Unk, Unk		Sanofi
	Plaquenil			S		Unk Unk, Unk		Sanofi
	Sulfasalazine			S		Unk Unk, Unk		Not Reported
	Sulfasalazine			S		500 Mg, Unk		Not Reported
	Sodium Aurothiomalate			S		Unk Unk, Unk		Not Reported
	Sodium Aurothiomalate			S		Unk Unk, Unk		Not Reported
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Anakinra			S	Unknown	Unk Unk, Unk		Not Reported
	Anakinra			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk, Unk		Not Reported

	Gold	S	Unknown	Unk Unk, Unk	Not Reported
	Humira	S		Unk Unk, Unk	Not Reported
	Humira	S	Subcutaneous	Unk Unk, Unk	Not Reported
	Ilaris	S	Subcutaneous	Unk Unk, Unk	Not Reported
	Ilaris	S	Subcutaneous	Unk Unk, Unk	Not Reported
	Orencia	S		Unk Unk, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk Unk, Unk	Not Reported
	Remicade	S		Unk Unk, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk, Unk	Not Reported
	Rituxan	S		Unk Unk, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk, Unk	Not Reported
	Rituximab;Urelumab	C		Unk Unk, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	16884494	EXPEDITED (15-DAY)		OT	CA-ROCHE-2417965		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)			
	Leflunomide	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Mol		Not Reported
	Wellbutrin	C	Unknown	Tablet (Extendedrelease)		Not Reported
	Sulfasalazine	C				Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17241867	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511098		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Actemra			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17245016	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2511679		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Condition Aggravated; Drug Ineffective; Haematemesis; Hepatotoxicity; Jaundice; Joint Swelling; Nausea; Platelet Count Increased; Rheumatoid Arthritis; Treatment Failure; Vitamin D Decreased; Vomiting	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Rosuvastatin			C	Unknown			Not Reported
	Vitamin C [Ascorbic Acid]			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Ergocalciferol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17259884	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518729		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17278764	EXPEDITED (15-DAY)		OT	NVSC2019CA086426		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Decreased Appetite; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Hypoaesthesia; Infusion Related Reaction; Joint Swelling; Live Birth; Malaise; Mobility Decreased; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor	Diclofenac			S	Unknown	50 Mg		Novartis
	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Diclofenac Diethylamine			S	Unknown	Unk		Novartis
	Cetirizine Hydrochloride			S	Unknown	10 Mg		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg		Not Reported
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Folic Acid			S	Unknown	0.5 Unk		Not Reported
	Folic Acid			S	Oral	25 Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Etanercept			S	Subcutaneous	50 Mg		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	400 Mg		Not Reported
	Cimzia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	400 Mg, Qw		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Qw		Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported

Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Humira	S	Subcutaneous	40 Mg, Qw	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Oral	5 Mg, Biw	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Unknown	Unk	Not Reported
	Apo Prednison	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Mg	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg, Qd	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Subcutaneous	Unk	Not Reported
	Salazopyrine	S	Oral	1 G, Bid	Not Reported
	Sulfasalazine	S	Oral	500 Mg	Not Reported
	Sulfasalazine	S	Oral	1000 Mg, Qd	Not Reported
	Paracetamol	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Tocilizumab	S	Subcutaneous		Not Reported
	Winpred	S	Oral		Not Reported
	Stelera	S	Unknown		Not Reported
	Topicort	S	Subcutaneous		Not Reported
	Topicort	S	Oral	Unk	Not Reported

Sarilumab	S	Unknown			Not Reported
Apo-Hydroxyquine	S	Unknown			Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk		Not Reported
Apremilast	S	Unknown	Unk		Not Reported
Tofacitinib Citrate	C	Unknown			Not Reported
Salazopyrin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17396502	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-007504			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Prednisone			S	Intravenous (not	Unk		Not Reported

			otherwise specified)			
	Prednisone	S	Unknown	Unk		Not Reported
	Diclofenac	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Tocilizumab	S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown			Not Reported
	Diclofenac Sodium	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Etanercept	S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17594370	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA085524		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Ilaris			S	Subcutaneous	Unk		Novartis
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hidroxicloroquina			S	Unknown	Unk		Not Reported

	Orencia	S	Unknown	Unk		Not Reported
	Remicade	S	Unknown			Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17598822	EXPEDITED (15-DAY)		LT	NVSC2020CA085528		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Ilaris			S	Subcutaneous			Novartis
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unknown		Not Reported
	Urelumab			C	Unknown			Not Reported
	Rituximab			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17640700	EXPEDITED (15-DAY)		LT, OT	FR-SA-2020SA087400		18 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Cholestatic Liver Injury; Diabetic Metabolic Decompensation; Haemoglobin Decreased; Infection; Inflammation; Pyrexia; Respiratory Disorder	Hydroxychloroquine Sulfate			S	Other	1200 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Other	400 Mg, Qd		Sanofi
	Lovenox			S	Subcutaneous	0.6 Ml, Qd		Sanofi
	Midazolam			S	Intravenous (not otherwise specified)	5 Mg/Ml, Qd		Not Reported
	Omeprazole			S	Intravenous (not otherwise specified)	20 Mg, Qd		Not Reported
	Omeprazole			S	Intravenous (not otherwise specified)	40 Mg, Qd		Not Reported
	Loxen [Loxoprofen Sodium]			S	Intravenous (not otherwise specified)	30 Mg, Qd		Not Reported
	Movicol [Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Ch			S	Other	2 Df Bag		Not Reported
	Paracetamol			C	Other	4 G, Qd		Not Reported
	Paracetamol			C				Not Reported
	Lasilix [Furosemide]			C	Other	30 Mg, Qd		Not Reported
	Novorapid			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Doliprane			C				Not Reported
	Doliprane			C				Not Reported
	Diffu K			C	Other	3.6 G, Qd		Not Reported
	Diffu K			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17662286	EXPEDITED (15-DAY)		DE, HO, LT, OT	FR-ADVANZ PHARMA-202003002885			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiac Arrest; General Physical Health Deterioration; Off Label Use; Pneumonia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil		S	Unknown	Unk (Film Coated Tablet)	Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil		S			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17688286	EXPEDITED (15-DAY)		OT	JP-ABBVIE-20K-087-3369108-00		58 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Gastrointestinal Disorder; General Physical Health Deterioration; Off Label Use	Kaletra			S	Oral	800 / 200 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17708221	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202003002358			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Off Label Use; Pneumonia; Respiratory Failure	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	At 800mg Loading Dose (400 Mg, Bid (Fiim-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		400 Mg, Qd		Concordia
	Enoxaparin			C		Unk		Not Reported
	Enoxaparin			C				Not Reported
	Paracetamol			C		Unk		Not Reported
	Etomidate			C		Unk		Not Reported
	Celocurine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17715835	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245249		52 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatitis	Azithromycin	S	Oral	500 Mg Dia	Sun
	Paracetamol	S	Oral	1gr Cada 8 Horas	Ohm Lab
	Simvastatina Alter 10 Mg Comprimidos Recubiertos Con Pelicula Efg ...	S	Oral	0-0-1 ()	Not Reported
	Dolquine 200 Mg Comprimidos, 30 Comprimidos	S	Oral	400 Mg Dia	Not Reported
	Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	2 Gr Dia	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17727001	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202004004251			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Respiratory Tract Infection Fungal	Hydroxychloroquine			S	Oral	600 Mg, Qd, Film-Coated Tablet		Concordia
	Hydroxychloroquine			S	Oral	400 Mg, Qd, Film-Coated Tablet		Concordia
	Imipenem			C		Unk		Not Reported
	Lansoprazole			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Chlorpromazine			C		Unk		Not Reported
	Dexmedetomidine			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Urapidil			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17731811	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590211			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Deformity; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Rituxan	S	Intravenous drip	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Urethral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17732418	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245759		53 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Propofol Infusion Syndrome	Azithromycin			S	Oral	500 Mg Dia		Sun
	Propofol 2% Inyectable Baxter, 1			S	Intravenous (not otherwise specified)	Sedacion		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg Dia		Not Reported
	Dexametasona (722a)			C	Intravenous (not otherwise specified)	4 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17741948	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-021386		78 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin Film-Coated Tablets		S	Oral	500 Milligram, Once A Day	Aurobindo
	Plaquenil		S	Oral	600 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742093	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-035046		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cough; Drug Ineffective; Headache; Product Use Issue; Rheumatoid Arthritis; Viral Infection	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Xeljanz			S	Oral	50 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742136	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231902		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Risedronate Sodium			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)			
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	300 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742350	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004004645			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antiphospholipid Syndrome	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742372	EXPEDITED (15-DAY)		LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245940		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Risperidone			S	Oral	2 Milligrams, Daily		Sun
	Plaquenil 200 Mg, Comprime Pellicule			S	Oral	600 Milligrams, Daily		Not Reported
	Effexor L.P. 75 Mg, Gelule A Liberation Prolongee			S	Oral	150 Milligrams, Daily		Not Reported
	Acebutolol (Chlorhydrate D')			C	Oral	400 Milligrams, Daily		Not Reported
	Oxazepam			C	Oral	100 Milligrams, Daily		Not Reported
	Enoxaparine Sodique ((Mammifere/Porc/Muqueuse Intestinale))			C	Subcutaneous	4000 International Unit, Daily		Not Reported
	Macrogol 4000			C	Oral	2 Dosage Form, Daily		Not Reported
	Amlodipine			C	Oral	10 Milligrams, Daily		Not Reported
	Chlorhydrate De Clomipramine			C	Oral	150 Milligrams, Monthly		Not Reported
	Zopiclone			C	Oral	7.5 Milligrams, Daily		Not Reported
	Chlorhydrate De Nicardipine			C	Oral	60 Milligrams, Daily		Not Reported
	Hydrochlorothiazide			C	Oral	25 Milligrams, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742377	EXPEDITED (15-DAY)		LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245925		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Venlafaxine			S	Oral	225 Milligram, Daily		Sun
	Loxapine Base			S	Oral	155 Milligrams, Daily		Not Reported
	Plaquenil 200 Mg, Comprime Pellicule			S	Oral	600 Milligrams, Daily		Not Reported
	Theralene			S	Oral	50 Milligrams, Daily		Not Reported
	Paracetamol			C	Oral	1 Grams, Daily		Not Reported
	Nicopatch 7 Mg/24 H, Dispositif Transdermique De 17,5 Mg/10 Cm^2			C	Transdermal	7 Milligrams, Daily		Not Reported
	Diazepam			C	Oral	10 Milligrams, Daily		Not Reported
	Atorvastatine			C	Oral	40 Milligram, Daily		Not Reported
	Nicotine			C	Oral	12 Milligram, Daily		Not Reported
	Macrogol 4000			C	Oral	Unk		Not Reported
	Nebivolol			C	Oral	7.5 Milligrams, Daily		Not Reported
	Zopiclone			C	Oral	7.5 Milligram, Daily		Not Reported
	Ramipril			C	Oral	1.25 Milligram, Daily		Not Reported
	Akineton			C	Oral	4 Milligram, 1 Minute		Not Reported
	Ezetimibe			C	Oral	10 Milligram, Daily		Not Reported
	Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet-Dose			C	Oral	75 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742389	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591039			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra	S	Unknown		Not Reported
	Rituxan	S	Intravenous drip		Not Reported
	Acetaminophen	S	Unknown		Not Reported
	Acetaminophen	S	Unknown		Not Reported
	Apo-Acetaminophen	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	Therapy Duration 823 Nos	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Hydromorphone Hcl	C			Not Reported
	Methotrexate	C	Unknown		Not Reported
	Meloxicam	C			Not Reported
	Leflunomide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742455	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592060		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Azathioprine			S	Unknown			Not Reported

	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742519	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592094		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-Reactive Protein Increased; Diverticulitis; Drug Ineffective; Drug Intolerance; Infection; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742535	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004004726			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cornea Verticillata	Hydroxychloroquine			S		600 Mg, Bid		Concordia

Everolimus	C	10 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742575	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232090		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis; Therapeutic Response Decreased	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Acetaminophen			C				Not Reported
	Arava			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Elavil			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Imitrex [Sumatriptan]			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Premarin			C	Unknown			Not Reported
	Sumatriptan Succinate			C	Unknown			Not Reported
	Tenormin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742581	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232139		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	25 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742586	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232163			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Polyneuropathy	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742590	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232148			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742663	EXPEDITED (15-DAY)		DE, OT	IR-BEH-2020117003			Unknown	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Foetal Heart Rate Decreased; Maternal Exposure Timing Unspecified; Maternal Exposure Timing Unspecified	Human Immunoglobulin (Inn)			S	Intravenous (not otherwise specified)	20 Milligram, Qd		Csl Behring
	Oseltamivir			S	Oral			Not Reported
	Ceftriaxone			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin			S	Oral			Not Reported
	Kaletra			S	Oral			Not Reported

Oxygen	S	Unknown			Not Reported
Fentanyl	S	Unknown			Not Reported
Propofol	S	Unknown			Not Reported
Cisatracurium	S	Unknown			Not Reported
Red Blood Cells	S	Unknown	Unk		Not Reported
Red Blood Cells	S	Unknown	Unk		Not Reported
Vancomycin	S	Intravenous (not otherwise specified)			Not Reported
Meropenem	S	Intravenous (not otherwise specified)			Not Reported
Plasma, Fresh Frozen	S	Unknown	2 Units		Not Reported
Norepinephrine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742670	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591905			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Pulmonary Toxicity	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742768	EXPEDITED (15-DAY)		HO	CA-ROCHE-2592005		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742782	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034928		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, 1 Every 1 Day		Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Decreased; Myocardial Infarction; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram, Qwk	Not Reported
	Plaquenil S	S	Unknown		Not Reported
	Prednisolone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Risedronate Sodium	S	Unknown	5 Milligram	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	500 Milligram	Not Reported
	Cyclobenzaprine	C	Unknown	10 Milligram	Not Reported
	Desoximetasone	C	Unknown	5 Milligram, 1 Every 1 Day	Not Reported
	Leflunomide	C	Unknown		Not Reported
	Prednisone Acetate	C	Unknown	5 Milligram, 1 Every 1 Day	Not Reported
	Tylenol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742941	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588925		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17742971	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591836			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Rash	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Gabapentin			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17743291	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590858			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Leflunomide			C				Not Reported
	Orencia			C				Not Reported
	Tofacitinib Citrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17743295	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232132		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17743297	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245987		54 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg/24h		Sun
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2gr/24h		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	200 Mg/12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17743508	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591144		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Simponi			S	Subcutaneous					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17743620	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-246009		28 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Sun
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg Dia		Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported
	Paracetamol			S	Intravenous (not otherwise specified)	1gr Cada 8 Horas		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17743624	EXPEDITED (15-DAY)		DE	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-246005		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Tachyarrhythmia	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Hidroxicloroquina Sulfato			S	Oral	200 Milligram, Daily		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	()		Not Reported
	Ceftriaxona			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17743627	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-246048		52 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Hepatitis Cholestatic	Azithromycin		S	Oral	500 Mg Dia	Sun
	Ceftriaxona		S	Intravenous (not otherwise specified)	2 G Dia	Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos		S	Oral	400 Mg Dia	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17743715	EXPEDITED (15-DAY)		HO	CA-ROCHE-2591859			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17743716	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591858		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Pain; Spinal Compression Fracture; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17743721	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034889		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Infection; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Actonel			S	Unknown	35 Milligram, Qwk		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram		Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Oral	20 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram		Not Reported
	Plaquenil S			S	Unknown	300 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Rituximab	S	Intravenous (not otherwise specified)	1 Gram		Not Reported
Simponi	S	Subcutaneous			Not Reported
Xeljanz	S	Oral	5 Milligram, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17743801	EXPEDITED (15-DAY)		HO, OT	CN-ADVANZ PHARMA-202004004658			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Hepatic Enzyme Increased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk,		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		One Week After The Patient Started Tiated Hydroxychloroquine		Concordia
	Doxycycline Hyclate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17744109	EXPEDITED (15-DAY)		HO, LT	FR-MYLANLABS-2020M1043507		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Extrasystoles; Ventricular Tachycardia	Azithromycin			S	Oral	500 Mg J1 Puis 250 Mg Par Jour		Not Reported
	Plaquenil /00072603/			S	Oral	600 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17744126	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590175		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis; Contraindicated Product Administered; Drug	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17744353	EXPEDITED (15-DAY)		HO, OT	JP-LUPIN PHARMACEUTICALS INC.-2020-01836		41 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Infarction; Intrapartum Haemorrhage; Maternal Exposure During Pregnancy; Pelvic Infection; Placenta Accreta; Post Procedural Complication	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17744433	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592105		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Aspirin [Acetylsalicylic Acid]	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17744998	EXPEDITED (15-DAY)		OT	ES-SA-2020SA115661		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg Day		Sanofi
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Enoxaparin Sodium			S	Subcutaneous	60 Mg 24 Hours		Sanofi
	Enoxaparin Sodium			S	Subcutaneous	40 Mg, Qd		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17745259	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020175440		54 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug-Induced Liver Injury	Azithromycin			S	Oral	500 Mg, Daily (500 Mg/24h)		Pfizer
	Azithromycin			S				Pfizer
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, Daily (2gr/24h)		Not Reported
	Ceftriaxone			S				Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, 2x/Day (200 Mg/12h)		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17745263	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020175443		52 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis Cholestatic; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, 1x/Day		Not Reported
	Dolquine			S	Oral	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17745649	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230665			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Erythema; Gastric Ulcer; Hepatic Function Abnormal; Liver Function Test Increased; Skin Exfoliation	Amlodipine Besilate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Naproxen			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	300 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17745843	EXPEDITED (15-DAY)		OT	SI-TEVA-2020-SI-1228870		68 YR	Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Sumamed 500 Mg			S	Intravenous (not otherwise specified)	200 Mg		Not Reported
	Hydroxychloroquine Sulfate 200 Mg			S	Oral	200 Mg,The First Day 1000mg, Then 500mg, Therapy Lasted For 3 Days		Teva

	Midazolam	C	Not Reported
	Lopinavir/Ritonavir	C	Not Reported
	Paracetamol	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17746040	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1230156		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hyponatraemia	Levofloxacino (2791a)			S	Oral	500 Milligram Daily;		Teva
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	4 Dosage Forms Daily;		Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17746046	EXPEDITED (15-DAY)		LT	FR-PFIZER INC-2020178138		27 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Sinus Bradycardia	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17746077	EXPEDITED (15-DAY)		LT	FR-PFIZER INC-2020178133		64 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hypotension; Off Label Use; Product Use In	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	600 Mg, 1x/Day		Not Reported

Unapproved Indication;
Sinus Bradycardia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17746092	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591180		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Tofacitinib Citrate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Cymbalta			C				Not Reported
	Hydromorphone			C				Not Reported
	Remicade			C				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17746179	EXPEDITED (15-DAY)		DE, OT	IR-BEH-2020117006			Unknown	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Foetal Heart Rate Decreased; Maternal Exposure Timing	Human Immunoglobulin (Inn)			S	Intravenous (not otherwise specified)	20 Milligram, Qd		Csl Behring

Unspecified; Maternal Exposure Timing Unspecified	Oseltamivir	S	Oral			Not Reported
	Ceftriaxone	S	Oral			Not Reported
	Hydroxychloroquine	S	Oral			Not Reported
	Azithromycin	S	Oral			Not Reported
	Kaletra	S	Oral			Not Reported
	Oxygen	S	Unknown			Not Reported
	Fentanyl	S	Unknown			Not Reported
	Propofol	S	Unknown			Not Reported
	Cisatracurium	S	Unknown			Not Reported
	Red Blood Cells	S	Unknown	Unk		Not Reported
	Red Blood Cells	S	Unknown	Unk		Not Reported
	Vancomycin	S	Intravenous (not otherwise specified)			Not Reported
	Meropenem	S	Intravenous (not otherwise specified)			Not Reported
	Plasma, Fresh Frozen	S	Unknown	2 Units		Not Reported
	Norepinephrine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17746206	EXPEDITED (15-DAY)		OT	IR-BEH-2020117007			Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death; Haemoglobin Decreased; No Adverse Event; Product Use In Unapproved Indication	Human Immunoglobulin (Inn)			S	Intravenous (not otherwise specified)	20 Milligram, Qd		Csl Behring
	Oseltamivir			S	Oral			Not Reported
	Ceftriaxone			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin			S	Oral			Not Reported
	Kaletra			S	Oral			Not Reported
	Oxygen			S	Unknown			Not Reported
	Oxygen			S				Not Reported

Fentanyl	S	Unknown	Unk		Not Reported
Propofol	S	Unknown	Injection For Intubation		Not Reported
Propofol	S	Unknown	Infusion For Mechanical Ventilation		Not Reported
Cisatracurium	S	Unknown			Not Reported
Red Blood Cells	S	Unknown	1 Unit		Not Reported
Red Blood Cells	S	Unknown	1 Unit		Not Reported
Vancomycin	S	Intravenous (not otherwise specified)			Not Reported
Meropenem	S	Intravenous (not otherwise specified)			Not Reported
Plasma, Fresh Frozen	S	Unknown	2 Units		Not Reported
Norepinephrine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17746335	EXPEDITED (15-DAY)		DE	US-SLATE RUN PHARMACEUTICALS-20US000055			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Electrocardiogram T Wave Abnormal; Off Label Use	Azithromycin Usp			S	Intravenous (not otherwise specified)	Unk		Hainan Poly Pharmaceutical
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk, Single		Not Reported
	Methotrexate			C	Unknown			Not Reported
	Steroids			C		Unk		Not Reported
	Steroids			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17746449	DIRECT	Y	DE			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Aspartate Aminotransferase Increased; Asthenia; Blood Alkaline Phosphatase Increased; Blood Fibrinogen Increased; Blood Lactate Dehydrogenase Increased; Blood Potassium Decreased; Hypertension; Hypoxia; Lymphopenia; Pneumonia; Respiratory Failure; Serum Ferritin Increased; Type 2 Diabetes Mellitus	Hydroxychloroquine Sulfate Tablets	S	Oral		Teva
	Doxycycline	C			Not Reported
	Azithromycin	C			Not Reported
	Ceftriaxone	C			Not Reported
	Ampicillin	C			Not Reported
	Tocilizumab	C			Not Reported
	Ns 1000 Ml	C			Not Reported
	Acetaminophen	C			Not Reported
	Albuterol Inhaler	C			Not Reported
	Ascorbic Acid	C			Not Reported
	Benazepril	C			Not Reported
	Enoxaparin	C			Not Reported
	Hydrochlorothiazide	C			Not Reported
	Zinc Sulfate	C			Not Reported
	Regular Insulin	C			Not Reported
	Neutraphos	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17746494	EXPEDITED (15-DAY)		OT	CA-SA-2020SA114129			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Desoximetasone			S	Oral			Sanofi
	Diclofenac Sodium			S				Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S				Not Reported
	Sulfasalazine			S		500 Mg		Not Reported
	Arava			S	Oral			Sanofi
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Prednisone			S	Oral			Not Reported

Pseudoephedrine Hydrochloride	S				Sanofi
Prednisone	S				Not Reported
Folic Acid	S		1 Mg		Not Reported
Folic Acid	S		5 Unk		Not Reported
Alendronate Sodium	S	Oral			Not Reported
Cimzia	S	Subcutaneous			Not Reported
Adalimumab	S	Subcutaneous	40 Mg		Not Reported
Cortisone Acetate	S	Topical	25 Mg		Not Reported
Etanercept	S	Subcutaneous			Not Reported
Methotrexate Sodium	S				Not Reported
Orencia	S	Subcutaneous			Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Phthalylsulfathiazole	S				Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Tocilizumab	S	Subcutaneous			Not Reported
Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17746917	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592525			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17747080	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1043943		77 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Thrombocytopenia	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Clexane			S	Subcutaneous	4 Kilo-International Unit, Qd		Mylan
	Plaquenil /00072602/			S	Oral	600 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17747258	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2592551			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17747361	EXPEDITED (15-DAY)		LT	FR-MYLANLABS-2020M1044977		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Risperidone			S	Oral	2 Milligram, Qd		Not Reported
	Effexor			S	Oral	150 Milligram, Qd		Mylan
	Plaquenil /00072603/			S	Oral	600 Milligram, Qd		Mylan
	Acebutolol			C	Oral	400 Milligram, Qd		Mylan
	Oxazepam			C	Oral	100 Milligram, Qd		Mylan
	Enoxaparine Sodique			C	Subcutaneous	4000 International Unit, Qd		Mylan
	Macrogol 4000			C	Oral	2 Dosage Form, Qd		Mylan
	Amlodipine			C	Oral	10 Milligram, Qd		Mylan
	Clomipramine Hydrochloride			C	Oral	150 Milligram, Monthly		Mylan
	Zopiclone			C	Oral	7.5 Milligram, Qd		Mylan
	Nicardipine Hydrochloride			C	Oral	60 Milligram, Qd		Mylan
	Hydrochlorothiazide			C	Oral	25 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17748223	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012927			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Minocycline Hydrochloride			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Leflunomide	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17748237	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012925		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Minocycline Hydrochloride			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	11862970	EXPEDITED (15-DAY)		OT	CA-ROCHE-1602815		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Carotid Arteriosclerosis; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Herpes Zoster; Joint Swelling; Limb Discomfort; Malaise; Nausea; Nodule; Osteoarthritis; Rectal Haemorrhage; Thyroid Cancer	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Oral	Therapy Duration: 730 Nos		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	12962974	EXPEDITED (15-DAY)		OT	CA-ROCHE-1857489			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical Device Implantation	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)	
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	12967628	EXPEDITED (15-DAY)		DS	CA-ROCHE-1857523			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Drug Ineffective; Foot Operation; Loss Of Consciousness; Mobility Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	13057780	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2016AP015710		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Gait Inability; Headache; Herpes Zoster; Rheumatoid Arthritis	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Aspirin /00002701/			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported
	Prednisone			C	Unknown	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	13058749	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015733		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthritis; Condition Aggravated; Drug Ineffective; Hormone Level Abnormal; Immobile; Intentional Product Misuse; Loss Of Personal	Leflunomide			S	Oral	20.0 Mg, Qd		Apotex
	Mefenamic Acid			S	Unknown	400 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex

Independence In Daily Activities; Menopausal Symptoms; Menopause; Mobility Decreased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel	S	Subcutaneous	50 Mg, Unk	Not Reported
	Enbrel	S	Unknown	1 Df, Unk	Not Reported
	Enbrel	S	Unknown	50 Mg, Unknown	Not Reported
	Enbrel	S	Unknown	Unk Unk, Unknown	Not Reported
	Enbrel	S	Unknown	Unk Unk, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Oral	20 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Plaquenil /00072602/	S	Oral	400 Mg, Unk (Therapy Duration 730 Unit Unspecified)	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk, Bid	Not Reported
	Advil /00044201/	S	Unknown	400 Mg, Bid	Not Reported
	Arava	S	Unknown	20 Mg, Qd	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	13063060	EXPEDITED (15-DAY)		OT	CA-ROCHE-1631753			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Liver Injury; Loss Of Personal Independence In Daily Activities; Migraine; Neck Pain; Nodule; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling;	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Not Controlling Disease And Causing Debilitation And Inability To Perform Daily Activities		Not Reported
	Humira			S	Subcutaneous	Didn'T Work And Patient Still Symptomatic		Not Reported
	Leflunomide			S	Unknown	Didn'T Work And Patient Still Symptomatic		Not Reported

Swelling; Therapeutic Product Effect Decreased	Sulfasalazine	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Affected Liver Enzymes	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported
	Methotrexate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	13099718	EXPEDITED (15-DAY)		OT	CA-ROCHE-1876546			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Estradiol			C				Not Reported
	Furosemide			C				Not Reported
	Valsartan			C				Not Reported
	Xalatan			C				Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C				Not Reported
	Atasol With Codeine-Caffeine			C				Not Reported
	Acetaminophen			C				Not Reported
	Ergocalciferol			C				Not Reported
	Estrogel			C				Not Reported
	Gravol			C				Not Reported

	Levaquin	C	Not Reported
	Potassium Chloride	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	13254176	EXPEDITED (15-DAY)		HO	CA-ROCHE-1893244		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Joint Laxity; Multiple Fractures; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	13254292	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006753		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Cytology Abnormal; Drug Intolerance; Joint Swelling; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine	S	Unknown	200 Mg, Bid	Apotex
	Apo-Leflunomide	S	Unknown	20 Mg, Qd, (Therapy Duration: 365 Unit Not Reported)	Apotex
	Apo-Leflunomide	S	Unknown	11.2 Mg, Qd (Therapy Duration: 365 Unit Not Reported)	Apotex
	Leflunomide	S	Unknown	20 Mg, Qd, Thepay Duration 365 Unit Not Reported	Apotex
	Sulfasalazine	S	Unknown	1 G, Qd	Not Reported
	Methotrexate	S	Unknown	20 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	20 Mg, Q.Wk.	Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown	20 Mg, Qd	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Rituximab	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Unknown	200 Mg, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	1 G, Qd	Not Reported
	Lyrica	C	Oral		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Prednisone	C	Unknown	15 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	13280419	EXPEDITED (15-DAY)		OT	CA-ROCHE-1681465			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased; Therapeutic Response Decreased; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 3 Years		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 4 Years		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 8 Years		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 9 Years		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 9 Years		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 10 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Subcutaneous	Therapy Duration: 21 Years		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Therapy Duration: 21 Years		Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	13300820	EXPEDITED (15-DAY)		OT	CA-ROCHE-1902134		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaphylactic Reaction; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Synovitis	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Abatacept	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Parenteral	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Actemra	S	Unknown	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Tofacitinib	C		Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	13303889	EXPEDITED (15-DAY)		OT	CA-ROCHE-1900072			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Tylenol	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Acetaminophen;Diphenhydramine Hydrochloride	S	Unknown	Not Reported
	Apo-Acetaminophen	S	Unknown	Not Reported

	Apo-Hydro	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Acetaminophen;Codeine Phosphate	C			Not Reported
	Leflunomide	C	Unknown	Therapy Duration: 4 Months	Not Reported
	Meloxicam	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported
	Celebrex	C			Not Reported
	Hydromorphone Hcl	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	13606666	EXPEDITED (15-DAY)		OT	CA-ROCHE-1941037			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown	Therapy Duration: 3 Years		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 9 Months		Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Therapy Duration: 2 Years Single-Use Prefilled Syringe		Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 730 Not Otherwise Specified		Not Reported

Enbrel	S	Unknown	Therapy Duration: 4 Years	Not Reported
Enbrel	S	Unknown	Therapy Duration: 731 Not Otherwise Specified	Not Reported
Humira	S	Subcutaneous	Therapy Duration: 5 Months	Not Reported
Humira	S	Unknown		Not Reported
Leflunomide	S	Unknown	Therapy Duration: 5 Months	Not Reported
Leflunomide	S	Unknown	Therapy Duration: 1 Month	Not Reported
Methotrexate	S	Subcutaneous	Therapy Duration: 8 Years	Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 2 Years	Not Reported
Remicade	S	Unknown		Not Reported
Simponi	S	Subcutaneous	Therapy Duration: 2 Months	Not Reported
Simponi	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Diclofenac Sodium/Misoprostol	S	Unknown		Not Reported
Diclofenac Sodium/Misoprostol	S	Unknown		Not Reported
Imuran [Azathioprine]	C			Not Reported
Vitamin D3	C	Unknown		Not Reported
Arthrotec	C	Unknown		Not Reported
Clindamycin	C			Not Reported
Cloxacillin	C			Not Reported
Plaquenil [Hydroxychloroquine	C	Unknown		Not Reported

	Sulfate]									
	Ergocalciferol			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	13704329	EXPEDITED (15-DAY)		OT	CA-ROCHE-1955170			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Arthralgia; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Dexamethasone			C				Not Reported
	Acetaminophen			C				Not Reported
	Gabapentin			C				Not Reported
	Reactine [Cetirizine Hydrochloride]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	13915547	EXPEDITED (15-DAY)		OT	CA-ROCHE-1982329		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pain; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			C	Oral	Therapy Duration: 365 Days		Not Reported
	Hydroxychloroquine			C	Oral	Therapy Duration-365		Not Reported
	Hydroxychloroquine			C	Oral			Not Reported
	Hydroxychloroquine			C	Oral			Not Reported
	Leflunomide			C	Oral	Therapy Duration: 549 Days		Not Reported
	Orencia			C				Not Reported
	Xeljanz			C	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Tofacitinib Citrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	13948093	EXPEDITED (15-DAY)		OT	CA-ROCHE-1708212			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	4 Months		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	13974176	EXPEDITED (15-DAY)		HO, LT, OT	CA-APOTEX-2017AP017989			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S				Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S				Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S				Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Enbrel	S				Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Humira	S	Unknown	Unk		Not Reported
Ilaris	S	Subcutaneous	Unk		Not Reported
Ilaris	S	Unknown	Unk		Not Reported
Methotrexate	S	Intra-arterial	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Orencia	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S	Unknown	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Sulfasalazine	S				Not Reported
Plaquenil /00072602/	S	Unknown	Unk		Not Reported
Plaquenil /00072602/	S				Not Reported
Gold	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	14128207	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP020228		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; No Adverse Event; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

Methotrexate Sodium	S	Unknown	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Plaquenil /00072602/	S	Unknown	Unk		Not Reported
Remicade	S	Unknown	Unk		Not Reported
Rituxan	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Naproxen	C	Unknown	500 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	14152209	EXPEDITED (15-DAY)		HO	CA-ROCHE-2013407			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	14235033	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021680		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, B.I.Wk.		Not Reported
	Enbrel			S	Unknown	25 Mg, Unk		Not Reported
	Humira			S	Unknown	40 Mg, Q.O.Wk.		Not Reported
	Methotrexate			S	Unknown	20 Mg, Q.Wk.,731.0		Not Reported
	Methotrexate			S	Unknown	15 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	15 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown	300 Mg, Once Every 6 Weeks		Not Reported
	Remicade			S	Unknown	300 Mg, Once Every 6 Weeks		Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	14242686	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021958		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Q.Wk.		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Asa			C	Unknown	81 Mg, Unk		Not Reported
	Clonazepam			C	Oral	0.5 Mg, Unk		Not Reported
	Desipramine			C	Unknown	50 Mg, Unk		Not Reported
	Gabapentin			C	Oral	300 Mg, Unk		Not Reported
	Nitroglycerin			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Oral	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	14713133	EXPEDITED (15-DAY)		OT	CA-ROCHE-2095769		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Kineret			S	Subcutaneous	100mg Per Syringes Single-Use, Preservative-		Not Reported

					Free Prefilled Synringe; Solution Subcutaneous	
	Leflunomide		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Azathioprine		S	Unknown		Not Reported
	Azathioprine		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Gold		S	Intramuscular		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	14801305	EXPEDITED (15-DAY)		OT	CA-ROCHE-2109842			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Ill-Defined Disorder; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Oral			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Toradol	S	Unknown		Not Reported
	Prednisone	C			Not Reported
	Tramadol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	14849865	EXPEDITED (15-DAY)		OT	CA-ROCHE-2114738		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	15322930	EXPEDITED (15-DAY)		DS	CA-ROCHE-2174731		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Joint Swelling; Rheumatoid Arthritis; Wheelchair User	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Prefilled Syringe; Solution		Not Reported

				Subcutaneous	
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Aspirin [Acetylsalicylic Acid]	C	Unknown	Not Specified	Not Reported
	Folic Acid	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	15342316	EXPEDITED (15-DAY)		OT	CA-ROCHE-2178182		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Arthrotec	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Imuran [Azathioprine]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	15449266	EXPEDITED (15-DAY)		OT	CA-ROCHE-2191560		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Leukopenia; Off Label Use; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17008473	EXPEDITED (15-DAY)		DS	CA-ROCHE-2454415			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hand Deformity; Hip Arthroplasty; Impaired Work Ability; Joint Swelling; Knee Arthroplasty; Polyarthritis; Rheumatoid Arthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Indometacin			S	Oral			Not Reported

Indometacin	S	Oral		Not Reported
Indometacin	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Indomethacin [Indometacin]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17023604	EXPEDITED (15-DAY)		DS	CA-ROCHE-2459894		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Arthropathy; Asthenia; C-Reactive Protein Increased; Cataract; Constipation; Drug Ineffective; Fatigue; Hepatic Cirrhosis; Herpes Zoster; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17042231	EXPEDITED (15-DAY)		HO	CA-ROCHE-2465088		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17042658	EXPEDITED (15-DAY)		HO	CA-ROCHE-2465443		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Abnormal; Surgery; Synovitis	Naproxen Sodium		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Xeljanz		S	Oral	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Folic Acid		C	Unknown	Not Reported
	Methotrexate		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17233344	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509589		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Supeudol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17240953	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019056593		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Inflammation;	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S		50 Milligram		Not Reported
	Enbrel			S		Unk		Not Reported

Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Pain; Therapeutic Product Effect Decreased	Humira	S	Subcutaneous	40 Milligram Solution	Not Reported
	Orencia	S		Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Kevzara	S		Unk	Not Reported
	Leflunomide	S		Unk	Not Reported
	Tocilizumab	S		Unk	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S		Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
	Sarilumab	S			Not Reported
	Folic Acid	C			Not Reported
	Rabeprazole Sodium	C	Oral	20 Milligram, Once Daily (Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17259828	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514035		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Limb Operation; Pain; Peripheral Swelling; Rash; Swelling; Tendon	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfamethoxazole/Trimethoprim			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported

Operation; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rocuronium	S	Unknown	Not Reported
	Rocuronium Bromide	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Penicillin-G	S	Unknown	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17412202	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202002000692			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Pain In Extremity; Pleural Effusion; Rheumatoid Arthritis; Rheumatoid Arthritis; Skin Infection	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17578035	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009106			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective;	Hydroxychloroquine			S	Unknown	Unk		Apotex

Fatigue; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus	Folic Acid	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Cetirizine	S	Unknown	10 Mg, Unk	Apotex
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cortisone Acetate	S	Topical	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Reactin /00884302/	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17580690	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023759		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb

Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Intentional Product Use Issue; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Leflunomide	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Xeljanz	S	Unknown	12.5 Milligram	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17605620	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200333278		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased;	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Vaginal			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Gold	S	Unknown			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Apo-Leflunomide	S	Oral	Cyclical		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine	S	Oral			Not Reported
	Leflunomide	S	Oral			Not Reported
	Risedronate	S	Unknown			Not Reported
	Risedronate	S	Unknown			Not Reported
	Risedronate Sodium	S	Oral			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17662281	EXPEDITED (15-DAY)			FR-ADVANZ PHARMA-202003002582			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17665011	NON-EXPEDITED			US-PFIZER INC-2020152441		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective For Unapproved Indication; Off Label Use	Enbrel	S	Unk	Unknown
	Methotrexate Sodium	S	Unk	Pfizer
	Humira	S	Unk	Not Reported
	Plaquenil	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17665283	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021759		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Hydroxychloroquine			S	Oral	2 Df, Qd		Apotex
	Hydroxychloroquine			S	Oral	5 Mg, Bid		Apotex
	Hydroxychloroquine			S	Oral	10 Mg, Qd		Apotex
	Hydroxychloroquine			S	Subcutaneous	Unk		Apotex
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Apotex
	Apo-Hydroxyquine			S	Oral	Unk		Apotex
	Apo-Leflunomide			S	Oral	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Cyclosporine			S	Oral	Unk		Apotex
	Cyclosporin			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.O.Wk.		Not Reported

Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate Sodium	S	Oral	20 Mg, Unk	Not Reported
Methotrexate Sodium	S	Oral	20 Mg, Unk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg, Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Oral	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituximab	S	Endocervical	Unk	Not Reported
Rituximab	S			Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S			Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Xeljanz	S	Oral	5 Mg, Bid	Not Reported
Xeljanz	S	Unknown	2 Df, Qd	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	Unk, Qd	Not Reported
Xeljanz	C	Oral	Unk	Not Reported
Xeljanz	C	Oral	10 Mg, Qd	Not Reported
Xeljanz Xr	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17670925	EXPEDITED (15-DAY)		DE, OT	ES-CIPLA LTD.-2020ES02594			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Levofloxacin			S	Unknown	Unk		Cipla
	Hidroxicloroquina Sulfato			S	Oral	200 Milligram, Per Day		Not Reported
	Azitromicina			S	Oral	500 Milligram, Per Day		Not Reported
	Lopinavir/Ritonavir			S	Oral	2 Dosage Form, Bid, (12 H)		Not Reported
	Tacrolimus			S	Oral	Unk		Not Reported
	Ceftriaxona [Ceftriaxone]			C	Unknown	Unk		Not Reported
	Enoxaparina Sodica			C	Subcutaneous	40 Milligram, Per Day		Not Reported
	Prednisona			C	Oral	20 Milligram, Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17671057	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009843			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, B.I.Wk.		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Unk (Cyclical)		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Unk Cyclical		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, T.I.W		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Q.O.Wk.		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Subcutaneous	20 Mg, Q.Wk.		Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Sulfasalazine	S	Unknown	Unk		Not Reported
Enbrel	S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
Actemra	S	Subcutaneous	162 Mg, B.I.Wk.		Not Reported
Actemra	S	Subcutaneous	162 Mg, Q.O.Wk.		Not Reported
Adalimumab	S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
Adalimumab	S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
Prednisone	C	Unknown	20 Mg, Qd		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported
Leflunomide	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17688373	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP016273		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Pain; Pemphigus; Rash; Rheumatoid Factor Positive; Swelling; Systemic Lupus Erythematosus; Wound	Folic Acid			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Hydroxychloroquine			S		Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Cetirizine			S	Unknown	Unk		Apotex
	Methotrexate			S	Oral	25 Mg, Unk		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Reactine /00884302/	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Plaquenil /00072602/	S	Oral	Every One Day	Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Cutaneous	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Topicort /00028604/	S	Cutaneous	Unk	Not Reported
	Xeljanz	C	Unknown		Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17688732	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200411522		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Blood Pressure Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gout; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Metabolic	Simponi			S	Subcutaneous			Janssen
	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Surgery; Middle Insomnia; Migraine; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Off Label Use; Osteomyelitis; Pain In Extremity; Peripheral Swelling; Product Use Issue; Rheumatoid Arthritis; Sensitivity To Weather Change; Swelling; Synovitis; Therapeutic Product Effect Decreased; Weight Increased	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Celebrex	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Allopurinol	C	Unknown		Not Reported
	Clomipramine	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Pantoloc /01263201/	C	Unknown		Not Reported
	Zyloprim	C	Unknown		Not Reported
	Fentanyl	C	Unknown	Transdermal Patch	Not Reported
	Fentanyl Citrate	C	Unknown	Liquid Epidura	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17689640	EXPEDITED (15-DAY)		DE, HO, OT	SK-BAXTER-2020BAX007949		57 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Bulbar Palsy; Cardiac Arrest; Cerebral Infarction; Dizziness; Hypotension; Intentional Product Use Issue; Jc	Endoxan 1000 Mg Prasok Na Injekcny Roztok			S	Unknown	Unk		Baxter
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

Virus Infection; Mental Impairment; Off Label Use; Pneumonia; Progressive Multifocal Leukoencephalopathy; Respiratory Failure; Speech Disorder; Tremor	Azathioprine		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Cyclosporine A		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Belimumab		S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil		S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17699793	EXPEDITED (15-DAY)		OT	CA-ROCHE-2586666		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Piroxicam			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Pregabalin			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Teva Mycophenolate	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17713157	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2020161842		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dementia; Drug Ineffective; Pneumonia; Weight Decreased	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S		200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17715830	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245242		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Azithromycin			S	Oral	500 Mg Dia		Sun
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400mg Dia		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17729805	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2020171215		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis Acute; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day (500 Mg Day)		Pfizer
	Azithromycin			S				Pfizer
	Dolquine			S	Other	400 Mg, Daily (Via Nasogastric Tube)		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17732183	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590384		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Joint Swelling; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17748264	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591079		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not			Not Reported

					otherwise specified)					
	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17748315	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592025		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Actemra			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17748502	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-021696		43 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Paracetamol			S	Oral	1 Gram, 3 Times A Day		Aurobindo
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17748521	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-022017		57 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Hepatitis	Azithromycin	S	Oral	500 Milligram, Dia	Aurobindo
	Roactemra	S	Intravenous (not otherwise specified)	600 Milligram	Not Reported
	Roactemra	S			Not Reported
	Lopinavir;Ritonavir	S	Oral	2 U, Two Times A Day	Not Reported
	Lopinavir;Ritonavir	S			Not Reported
	Hidroxicloroquina	S	Oral	400 Milligram, Dia	Not Reported
	Hidroxicloroquina	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17748548	EXPEDITED (15-DAY)		LT	FR-CADILA HEALTHCARE LIMITED-FR-ZYDUS-050103			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Olanzapine			S	Oral	7.5 Milligram, Qd		Zydus Pharm
	Plaquenil Sulfate			S	Oral	800 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17748701	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-022018		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Long Qt Syndrome	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S				Not Reported
	Roactemra			C	Intravenous (not otherwise specified)	600 Milligram,1 Total		Not Reported
	Roactemra			C				Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17748835	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591229		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Carpal Tunnel Syndrome; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Knee Arthroplasty; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17749054	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593194			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17749117	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592495			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C				Not Reported
	Simponi			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17749213	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592694		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Synovitis; Throat Tightness	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Supeudol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17749294	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593188			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17749417	EXPEDITED (15-DAY)		HO	CA-ROCHE-2591882			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product	Tocilizumab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting	Naproxen Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17749452	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592483		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Back Disorder; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Mouth Ulceration; Vasculitic Rash	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17749505	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593219			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Acetaminophen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17749626	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590880			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

	Prednisone	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17749765	EXPEDITED (15-DAY)		OT	NVSC2020IR111437		24 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Osteonecrosis	Prednisolone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17749788	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1230789		51 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Hidroxicloroquina (2143a)			S	Oral	800 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17749846	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202004004835			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Hydroxychloroquine			S		7 Little Pills		Concordia
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17749889	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590257		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Actemra			S	Unknown			Not Reported
	Amoxicillin Sodium;Clavulanate Potassium			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tridural			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C				Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17750016	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2590470		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Ineffective; Intentional Product Use Issue; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S		Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cannabis Sativa	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S		Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Ilaris	S	Unknown	Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Minocycline	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported

Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17750116	EXPEDITED (15-DAY)		DE, HO	ES-TEVA-2020-ES-1230679		70 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Bundle Branch Block Right; Hypertension; Hypofibrinogenaemia; Pneumonia Escherichia; Ventricular Tachycardia	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Azitromicina (7019a)			S	Intravenous (not otherwise specified)	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab (8289a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17750118	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1230310		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17750156	EXPEDITED (15-DAY)		HO	SE-ACCORD-180870		16 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Fatigue; Intentional Overdose; Intentional Self-Injury; Somnolence; Tachycardia	Sertraline			S	Oral	Intentional Overdose		Accord
	Prednisolone			S	Oral	10-15 St, Intentional Overdose		Not Reported
	Plaquenil			S	Oral	10-15 St, Intentional Overdose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17750216	NON-EXPEDITED			US-PFIZER INC-2020180158		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Joint Swelling; Peripheral Swelling	Sulfasalazine			S		Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Plaquenil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17750441	EXPEDITED (15-DAY)		OT	IN-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-245841		51 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Neurosensory; Glomerulonephritis Membranous	Hydroxychloroquine			S	Unknown	400 Milligram, Daily		Sun
	Prednisolone			C	Unknown	Unk (40 Mg/ Day Of Prednisolone With Gradual Taper To 5 Mg/Day And Maintained)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17750591	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592747		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	94.0 Days		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17750608	DIRECT	Y				53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immunodeficiency; Vomiting	Hydroxychloriquine		Y	S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17750700	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231666		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported

	Hydroxychloroquine Sulfate		S	Subcutaneous	400 Milligram Daily;	Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17750703	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592032			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sarilumab			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17750721	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-246167		73 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Haemorrhage; Hepatitis Acute	Azithromycin			S	Oral	500 Mg Dia		Sun
	Ertapenem (2881a)			S	Intravenous (not otherwise specified)	1 G Dia		Not Reported

	Piperacilina Tazobactam 4/0.5 G Polvo Para Solucion Inyectable Efg,...	S	Intravenous (not otherwise specified)	C/24 H		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S	Oral	400 Mg Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17750853	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593603			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17750989	EXPEDITED (15-DAY)		OT	CH-TEVA-2020-CH-1231349		72 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolytic Anaemia; Thrombocytopenia; Thrombotic Microangiopathy	Doxycycline			S	Oral			Actavis
	Azithromycin			S	Oral			Unknown
	Amoxicillin And Clavulanate Potassium			S	Intravenous drip			Teva

Plaquenil	S	Oral	800 Mg 22-23/03, 400 Mg 24-26/03, 600 Mg 26-30/03		Not Reported
Enoxaparin	S	Subcutaneous			Not Reported
Durogesic	S	Transdermal	Patch 25 Mcg/H : 1 Every 3 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17751018	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231681			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Constipation; Drug Hypersensitivity; Drug Ineffective; Rash; Rheumatoid Arthritis	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			C	Unknown	20 Milligram Daily;		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17751040	EXPEDITED (15-DAY)		HO	CA-ROCHE-2591815		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Ineffective; Fatigue; Loose Body In Joint; Osteoporotic Fracture; Pain; Synovitis	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17751253	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591867		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Inflammation; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17751361	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231392			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Inflammation; Local Reaction; Musculoskeletal Pain; Nausea; Neck Pain; Pain In Extremity; Rash; Syncope; Vomiting	Morphine Sulfate			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Aclasta			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plantago Afra			S	Unknown			Not Reported

	Remicade	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Asa	C	Unknown	81 Milligram Daily;	Not Reported
	Calcium Carbonate	C	Unknown		Not Reported
	Cannabis Sativa	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown	2000 Iu (International Unit) Daily;	Not Reported
	Folic Acid	C	Unknown		Not Reported
	Hydrochlorothiazide	C	Unknown		Not Reported
	Lipitor	C	Unknown	10 Milligram Daily;	Not Reported
	Methotrexate	C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17751521	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231640		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Rosuvastatin			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17751548	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020178177		45 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17751585	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020180060		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Condition Aggravated; Hepatocellular Injury; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported
	Rocephine			S	Oral	2 G, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17751680	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006814		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Apo-Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Oral	20 Mg, Unk		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex

Cyclosporine	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Oral	Unk	Not Reported
Sulfasalazine	S	Oral	500 Mg, Qd	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Q.O.Wk.	Not Reported
Humira	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	75 Mg, Q.M.T.	Not Reported
Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
Plaquenil /00072602/	S	Unknown	Unk	Not Reported
Adalimumab	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
Cimzia	S	Subcutaneous	200 Mg, Q.O.Wk.	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Endocervical	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	20 Mg, Unk	Not Reported
Methotrexate	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	20 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg, Unk	Not Reported

Xeljanz	S	Oral	5 Mg, Bid		Not Reported
Xeljanz	S	Unknown	2 Df, Qd		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Arava	C	Oral	20 Mg, Qd		Not Reported
Plaquenil /00072602/	C	Unknown	Unk		Not Reported
Risedronate	C	Oral	35 Mg, Q.Wk.		Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Xeljanz Xr	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17751718	EXPEDITED (15-DAY)		OT	NVSC2020FR120436		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Lamprene			S	Oral	100 Mg, Qd		Novartis
	Plaquenil			S	Oral	1 Df, Qd		Not Reported
	Noxafil			S	Oral	300 Mg, Qd		Not Reported
	Zithromax			S	Oral	250 Mg, Qd		Not Reported
	Ursodesoxycholic Acid			C	Unknown	Unk		Not Reported
	Propranolol			C	Unknown	Unk		Not Reported
	Ethambutol			C	Unknown	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Tramadol			C	Unknown	Unk		Not Reported
	Aldactone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17751868	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020178146		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Amlor			S	Oral	1 Df, 1x/Day		Pfizer
	Augmentin [Amoxicillin Trihydrate;Clavulanate Potassium]			S	Intravenous (not otherwise specified)	3 G, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, 1x/Day		Not Reported
	Colchimax [Colchicine;Papaver Somniferum Powder;Tiemonium Methylsulpha			S	Oral	1 Df, 1x/Day		Not Reported
	Paracetamol			S	Oral	4 G, 1x/Day		Not Reported
	Arimidex			S	Oral	1 Mg, 1x/Day		Not Reported
	Nefopam Hydrochloride			S	Oral	80 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17751882	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2020178687		73 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Haemorrhage; Hepatitis Acute; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, Daily		Pfizer
	Ertapenem			S	Intravenous (not otherwise specified)	1 G, Daily		Not Reported
	Piperacillin/Tazobactam			S	Intravenous (not otherwise specified)	C/24h		Not Reported
	Dolquine			S	Oral	400 Mg, Daily		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17751896	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020178145		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

Unapproved Indication

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752072	EXPEDITED (15-DAY)		HO	FR-CADILA HEALTHCARE LIMITED-FR-ZYDUS-050251			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Condition Aggravated; Hepatocellular Injury	Azithromycin			S	Oral	250 Milligram		Zydus Pharm
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Milligram		Not Reported
	Rocephine			S	Oral	2 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752139	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020178148		60 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752148	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA119135			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection;	Phenylephrine			S	Unknown	Unk		Novartis
	Benzalkonium Chloride			S	Unknown	Unk		Not Reported
	Diphenhydramine Hydrochloride		Y	S	Unknown	Unk		Not Reported
	Phenylephrine Hydrochloride			S	Unknown	Unk		Novartis
	Sulfasalazine			S	Oral	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

Joint Injury; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Bid	Not Reported
	Methotrexate	S	Oral	15 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Boric Acid	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Disodium Edetate	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	40 Mg, Qw	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Arava	S	Unknown	20 Mg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8.0 Mg/Kg, Qmo	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Rho D Immune Globulin	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Sodium Borate	S	Unknown	Unk	Not Reported
	Tofacitinib Citrate	S	Unknown	10 Mg, Q2w	Not Reported
	Tofacitinib Citrate	S	Unknown	10 Mg, Q2w	Not Reported
	Tofacitinib Citrate	S	Subcutaneous	10 Mg, Q2w	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported
	Ibuprofen	C	Unknown	Unk	Not Reported
	Lipitor	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752280	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592856			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Contraindicated Product Administered; Deformity; Ill-Defined Disorder; Malaise; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope	Actemra	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Anakinra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Codeine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752349	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592876		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatitis; Therapeutic Product Effect Decreased	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported

Humira	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Arava	C	Unknown	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported
Methotrexate	C	Subcutaneous	Not Reported
Methotrexate	C	Subcutaneous	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752382	EXPEDITED (15-DAY)		OT	US-AMNEAL PHARMACEUTICALS-2020-AMRX-01266		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Astigmatism; Cornea Verticillata	Hydroxychloroquine Sulfate			S	Unknown	600 Milligram, Bid (1200mg, 21.9 Mg/Kg/Day)		Amneal
	Everolimus			C	Unknown	10 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752490	EXPEDITED (15-DAY)		DS, HO, LT, OT	NVSC2020SK103006		31 YR	Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Growth Restriction; Maternal Exposure During Pregnancy; No Adverse Event; Oligohydramnios; Premature Baby	Cefotaxime			S	Unknown	Unk		Not Reported
	Cefotaxime			S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Novartis
	Omeprazole			S	Unknown	Unk		Not Reported
	Dexamethasone			S	Unknown	Unk		Not Reported

Dexamethasone	S	Unknown	Unk	Not Reported
Metoprolol Tartrate	S	Unknown	Unk	Not Reported
Acetaminophen (Paracetamol)	S	Unknown	Unk	Not Reported
Calcium Carbonate	S	Unknown	Unk	Not Reported
Cefixime	S	Unknown	Unk	Not Reported
Fluconazole	S	Unknown	Unk	Not Reported
Penicillin G Benzathine	S	Unknown	Unk	Not Reported
Vitamin K Nos	S	Unknown	Unk	Not Reported
Bisulepin	S	Unknown	Unk	Not Reported
Nadroparin Calcium	S	Unknown	Unk	Not Reported
Etamsylate	S	Unknown	Unk	Not Reported
Privigen	S	Unknown	Unk	Not Reported
Flebogamma Dif	S	Unknown	Unk	Not Reported
Potassium Chloride	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Vitamin B Complex	S	Unknown	Unk	Not Reported
Albumin	S	Unknown	Unk	Not Reported
Ornidazole	S	Unknown	Unk	Not Reported
Magnesium Lactate	S	Unknown	Unk	Not Reported
Methylprednisolone	S	Unknown	Unk	Not Reported
Methylprednisolone	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Amcal Hydrocortisone	S	Unknown	Unk	Not Reported
Vulmizolin	S	Unknown	Unk	Not Reported
Aminomethylbenzoic Acid	S	Unknown	Unk	Not Reported
Cc Vital Vitamin D [Cholecalciferol]	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752802	EXPEDITED (15-DAY)		LT	FR-MYLANLABS-2020M1045203		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use In Unapproved Indication; Torsade De Pointes; Ventricular Arrhythmia	Azithromycin			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752805	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1045208		28 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Azithromycin			S				Not Reported
	Dolquine			S	Oral	400 Mg Dia		Mylan
	Dolquine			S				Mylan
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	2 Gr Dia		Mylan
	Ceftriaxona /00672201/			S				Mylan
	Paracetamol			S	Intravenous (not otherwise specified)	1gr Cada 8 Horas		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752820	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1045211		63 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram, Total		Mylan
	Dolquine			S	Oral	400 Mg Dia		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752855	EXPEDITED (15-DAY)		DE	ES-MYLANLABS-2020M1045224		95 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Sudden Death	Quetiapine			S	Oral	25 Milligram, Qd		Not Reported
	Risperidone			S	Oral	1 Milligram, Qd		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Qd		Mylan
	Hidroxicloroquina Sulfato			S	Oral	200 Milligram, Bid		Mylan
	Levofloxacino /01278901/			S	Intravenous (not otherwise specified)	500 Milligram, Qd		Mylan
	Furosemida /00032601/			C	Oral	40 Milligram, Qd		Mylan
	Losartan			C	Oral	50 Milligram, Qd		Mylan
	Clindamicina /00166002/			C	Intravenous (not otherwise specified)	600 Milligram, Q6h		Mylan
	Lorazepam			C	Oral	1 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752857	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1045184		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Loss Of Consciousness; Malaise; Ventricular Extrasystoles	Azithromycin			S	Oral	Unk		Not Reported
	Plaquenil /00072603/			S	Oral	Unk		Mylan
	Lovenox			C	Oral	Unk		Mylan
	Paracetamol			C	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752859	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1045179		63 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis;	Azithromycin			S	Oral	500 Mg Dia		Not Reported

Hyperbilirubinaemia	Azithromycin		S			Not Reported
	Amoxicillin/Clavulanic Acid		S	Intravenous (not otherwise specified)	Cada 8 Horas	Not Reported
	Amoxicillin/Clavulanic Acid		S			Not Reported
	Dolquine		S	Oral	400 Mg Dia	Mylan
	Dolquine		S			Mylan
	Tocilizumab		S	Intravenous (not otherwise specified)	600 Mg Dia	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17753230	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592884		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Gait Disturbance; Nerve Compression	Actemra			S	Unknown	365.0		Not Reported
	Hydroxychloroquine			S	Unknown	5.0 Years		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	8.0 Years		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17753640	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-02		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Conjunctivitis; Drug Ineffective; Dyspnoea; Erythema; Haemoglobin Decreased; Infection; Joint Swelling; Musculoskeletal Pain; Nausea; Pain; Peripheral Swelling; Pneumonia; Pruritus; Rash;	Mobicox			S	Unknown			Boehringer Ingelheim
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Vimovo			S	Unknown	Tablet (Delayed And Immediate Release)		Not Reported
	Oxycocet			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

Rheumatoid Arthritis	Sulfamethoxazole And Trimethoprim	S	Unknown		Not Reported
	Septra	S	Unknown		Not Reported
	Ratio-Oxycocet	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown		Not Reported
	Methylprednisolone Sodium Succinate	S	Unknown		Not Reported
	Oxycodone And Acetaminophen	S	Unknown		Not Reported
	Naproxen	S	Unknown	Tablet (Enteric-Coated)	Not Reported
	Naproxen	S	Oral	Tablet (Enteric-Coated)	Not Reported
	Methotrexate	S	Subcutaneous	Solution	Not Reported
	Methotrexate	S	Oral		Not Reported
	Lyrica	S	Oral		Not Reported
	Imuran [Azathioprine]	S	Unknown		Not Reported
	Humira (Adalimumab)	S	Subcutaneous		Not Reported
	Esomeprazole	S	Unknown		Not Reported
	Esomeprazole Magnesium Trihydrate;Naproxen	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Elavil [Amitriptyline Pamoate]	S	Oral	Elavil Pamoate Syr 10mg/5ml	Not Reported
	Depo-Medrol	S	Intra-articular	Suspension Intra-Articular	Not Reported
	Bactrim	S	Unknown		Not Reported
	Apo-Ranitidine	S	Unknown		Not Reported
	Apo-Ranitidine	S	Oral		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Apo-Meloxicam	S	Unknown		Not Reported
	Apo-Amitriptyline	S	Oral		Not Reported
	Apo-Alendronate	S	Unknown		Not Reported
	Apo Naproxen	S	Unknown	Tablet (Entericcoated)	Not Reported

	Apo Naproxen	S	Unknown	Tablet (Entericcoated)	Not Reported
	Apo Naproxen	S	Oral	Tablet (Entericcoated)	Not Reported
	Amitriptyline	S	Oral		Not Reported
	Alendronate	S	Unknown		Not Reported
	Pantoloc [Pantoprazole]	S	Oral	Tablet (Entericcoated)	Not Reported
	Celebrex	C	Unknown		Not Reported
	Celecoxib	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17754146	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012923		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Minocycline			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Methotrexate	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Amoxicillin Sodium;Clavulanate Potassium	C	Unknown	Not Reported
	Amoxil	C	Unknown	Not Reported
	Bacillus Calmette-Guerin Bcg	C	Intravenous (not otherwise specified)	Not Reported
	Bacillus Calmette-Guerin Bcg	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17754149	EXPEDITED (15-DAY)		LT	CA-BAUSCH-BL-2020-012932		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain;	Minocycline Hydrochloride			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported

Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S		Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Marijuana	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Oxycodone	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S		Not Reported
	Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Xeljanz	S	Oral	Not Reported
	Kineret	C		Not Reported
	Lyrica	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17754163	EXPEDITED (15-DAY)		DE, LT	CA-BAUSCH-BL-2020-012936		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Minocycline Hydrochloride	S	Unknown		Not Reported
	Minocycline	S	Unknown		Not Reported
	Actemra	S	Unknown	Dosage Form Not Specified	Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S			Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S			Not Reported
	Gold	S	Unknown		Not Reported
	Gold	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported
	Ilaris	S	Unknown		Not Reported
	Ilaris	S	Subcutaneous		Not Reported
	Leflunomida	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S			Not Reported
	Marijuana	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S			Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported
	Oxycodone	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S			Not Reported
	Remicade	S	Unknown		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Kineret	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17754170	EXPEDITED (15-DAY)		DE	ES-BAUSCH-BL-2020-012998		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Sudden Death	Salbutamol (2297a)			S	Respiratory (inhalation)			Bausch And Lomb
	Dolquine			S	Oral	30 Tablets		Not Reported
	Metoclopramida (1958a)			S	Intravenous (not otherwise specified)			Not Reported
	Propofol (2373a)			S	Intravenous (not otherwise specified)			Not Reported
	Azitromicina (7019a)			S	Oral			Not Reported
	Ipratropio Bromuro (1067br)			C	Respiratory (inhalation)			Not Reported
	Cefotaxima (3840a)			C	Intravenous drip			Not Reported
	Midazolam (2256a)			C	Intravenous drip			Not Reported
	Enoxaparina Sodica (2482so)			C	Subcutaneous			Not Reported
	Tocilizumab (8289a)			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17754176	EXPEDITED (15-DAY)		HO, LT	CA-BAUSCH-BL-2020-012937			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Thrombosis; Urticaria	Minocycline Hydrochloride			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S				Not Reported
	Oxycodone			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Marijuana			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S		Not Reported
	Anakinra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17754231	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20180836875		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Not Reported

Dorzolamide Hydrochloride/Timolol Maleate	S	Ophthalmic	Not Reported
Folic Acid	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Levothyroxine Sodium	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Prednisone	S	Unknown	Not Reported
Ramipril	S	Oral	Not Reported
Codeine Phosphate	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Codeine	S	Unknown	Not Reported
Cosopt	S	Unknown	Not Reported
Acetaminophen	C	Unknown	Not Reported
Codeine Phosphate W/Paracetamol	C	Unknown	Not Reported
Tylenol	C	Unknown	Not Reported
Tylenol 2	C	Unknown	Not Reported
Acetaminophen W/Caffeine	C	Unknown	Not Reported
Plaquenil	C	Unknown	Not Reported
Diphenhydramine	C	Unknown	Not Reported
Methylprednisolone	C	Unknown	Not Reported
Hydroxychloroquine	C	Unknown	Not Reported
Acetaminophen W/Caffeine/Dihydrocodeine	C		Not Reported
Caffeine	C		Not Reported
Hydroxychloroquine Phosphate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17754512	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1230680		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Hepatitis	Hidroxicloroquina (2143a)	S	Oral	400 Milligram Daily;	Teva
	Azitromicina (7019a)	S	Oral	500 Milligram Daily;	Not Reported
	Azitromicina (7019a)	S			Not Reported
	Tocilizumab (8289a)	S	Intravenous (not otherwise specified)	600 Mg	Not Reported
	Paracetamol (12a)	S	Intravenous (not otherwise specified)	1gr Every 8 Hours	Not Reported
	Metamizol (111a)	S	Intravenous (not otherwise specified)	2gr Every 6 Hours	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17754709	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594253		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17754739	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594194		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cosentyx			S	Unknown			Not Reported

	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	11105334	EXPEDITED (15-DAY)		OT	CA-ROCHE-1574386			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous	Duration : 1095 Days		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Solution For Injection		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C		Not Reported
Synthroid	C		Not Reported
Lasix [Furosemide]	C	Unknown	Not Reported
Enablex [Darifenacin Hydrobromide]	C		Not Reported
Ativan	C		Not Reported
Loperamide	C	Unknown	Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown	Not Reported
Omnaris	C	Unknown	Not Reported
Pantoloc [Pantoprazole]	C		Not Reported
Vagifem	C	Vaginal	Not Reported
Cortisone	C	Intramuscular	Not Reported
Dilaudid	C	Unknown	Not Reported
Abatacept	C		Not Reported
Leflunomide	C		Not Reported
Kineret	C		Not Reported
Furosemide	C	Unknown	Not Reported
Diphenhydramine Hydrochloride	C		Not Reported
Darifenacin Hydrobromide	C		Not Reported

	Pantoprazole Sodium	C			Not Reported
	Oxyneo	C	Unknown		Not Reported
	Trimethoprim	C			Not Reported
	Restasis	C			Not Reported
	Kenalog [Triamcinolone Acetonide]	C			Not Reported
	Kadian	C	Unknown		Not Reported
	Codeine	C			Not Reported
	Acetaminophen	C			Not Reported
	Anakinra	C			Not Reported
	Desoximetasone	C			Not Reported
	Dexamethasone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	12098241	EXPEDITED (15-DAY)		OT	CA-ROCHE-1712937			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Actemra			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown	Dose Reduced		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Frequency: Every 1 Day; Therapy Duration: 4 Months, Stopped Due To Nausea,Vomiting, Intolerance		Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

	Methotrexate		S	Unknown	Not Reported
	Xeljanz		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	12810481	EXPEDITED (15-DAY)		OT	CA-ROCHE-1837479		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Pain; Pain	Actemra			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Tylenol			C	Unknown	As Required		Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	12881921	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP013278		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Multiple Fractures; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Naproxen Sodium Tablets			S	Unknown	Unk		Not Reported
	Naproxen			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Hydroxychloroquine			S				Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S				Apotex

	Naproxen Sodium	S	Unknown	Unk	Apotex
	Actemra	S	Unknown	Unk	Not Reported
	Aleve	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Unknown	12.5 Mg, Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	20 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Prednisone Acetate	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulphate	C	Unknown	Unk	Not Reported
	Folic Acid	C	Subcutaneous	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	20 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	12891035	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013489			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant;	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported

Onychoclasis; Tooth Loss	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	4omg/0.8ml	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Zostavax	S	Subcutaneous	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Xeljanz	C	Oral	10 Mg, Bid	Not Reported
	Cortisone /00014602/	C	Unknown	Unk	Not Reported
	Diclofenac /00372302/	C	Subcutaneous	100 Mg, Unk	Not Reported
	Cortisone Acetate	C	Subcutaneous	Unk	Not Reported
	Desoximetasone	C	Oral	Unk	Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	12923504	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1632295			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Off Label Use; Pain; Product Use Issue; Red Blood Cell	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported

Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate Sodium	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	Pre-Filled Syringe	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Anakinra	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Abatacept	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Methotrexate	C			Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	12981186	EXPEDITED (15-DAY)		OT	CA-ROCHE-1853913			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea;	Rituxan			S	Intravenous (not			Not Reported

Drug Hypersensitivity; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure			otherwise specified)		
	Actemra	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	Therapy Duration: 4 Years	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Single Use, Solution Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous	Therapy Duration: 8 Years	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Diclofenac Sodium/Misoprostol	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Arthrotec	C	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Therapy Duration: 8 Years	Not Reported
	Imuran [Azathioprine]	C	Unknown		Not Reported

	Vitamin D3	C	Oral		Not Reported
	Azathioprine	C			Not Reported
	Ergocalciferol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	13099777	EXPEDITED (15-DAY)		OT	CA-ROCHE-1595142		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Drug Ineffective; Impaired Work Ability; Infection; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Rituxan			S	Intravenous (not otherwise specified)	Cyclical, Therapy Duration: 8 Months		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Went Up To 25 Mg		Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 5 Months		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 7 Months		Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown	Did Not Work Therapy Duration: 3 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Therapy Duration: 3 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Actonel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	13099811	EXPEDITED (15-DAY)		OT	CA-ROCHE-1876558			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Contraindicated Product Administered; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Actemra			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	13103523	EXPEDITED (15-DAY)		OT	CA-ROCHE-1876554		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Off Label Use; Pain; Product Use In Unapproved Indication; Psoriatic Arthropathy; Rash; Red	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Intra-arterial			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Blood Cell Sedimentation Rate Increased; Rheumatic Disorder; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure	Arava	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Mycophenolate Mofetil Hydrochloride	S	Unknown	Not Reported
	Apo Mycophenolate	S	Unknown	Not Reported
	Mycophenolate	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Cimzia	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Piroxicam	C		Not Reported
	Leflunomide	C		Not Reported
	Morphine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	13116927	EXPEDITED (15-DAY)		OT	CA-ROCHE-1878962		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Arthritis; Synovitis; Transaminases Abnormal	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Remicade	S	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	13136489	EXPEDITED (15-DAY)		OT	CA-ROCHE-1882213		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Swelling	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	13233237	EXPEDITED (15-DAY)		OT	CA-ROCHE-1893773		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint	Actemra			S	Unknown			Not Reported

Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	13251590	EXPEDITED (15-DAY)		CA, OT	CA-APOTEX-2017AP006777		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Leflunomide			S	Unknown	10 Mg, Unk		Apotex
	Leflunomide			S	Unknown	10 Mg, Unk		Apotex
	Apo-Leflunomide			S	Oral	10 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	10 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	22.5 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	25 Mg, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

Sulfasalazine	S	Unknown	500 Mg, Bid		Not Reported
Sulfasalazine	S	Unknown	500 Mg, Bid		Not Reported
Prednisone	C	Oral	5 Mg, Qd		Not Reported
Prednisone	C	Unknown	5 Mg, Qd		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	13315469	EXPEDITED (15-DAY)		OT	CA-ROCHE-1808080		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Off Label Use; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cortisone			C	Unknown			Not Reported
	Cyclobenzaprine			C	Unknown	1/2 Tablet As Needed		Not Reported
	Tylenol			C	Unknown	As Needed		Not Reported
	Prednisone Acetate			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	13735259	EXPEDITED (15-DAY)		HO, LT, OT	CA-ROCHE-1356654		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Creatinine Increased;	Rituxan			S	Intravenous (not	Form Strength: 500 Mg/50		Not Reported

Blood Pressure Decreased; Blood Pressure Fluctuation; Blood Pressure Increased; Body Temperature Decreased; Cataract; Chills; Colitis Microscopic; Cough; Diarrhoea; Ear Pruritus; Fatigue; Headache; Hypertension; Hypotension; Hypotension; Hypotension; Malaise; Nasal Congestion; Nasopharyngitis; Nasopharyngitis; Oral Pruritus; Perforated Ulcer; Procedural Pain; Pyrexia; Renal Disorder; Single Functional Kidney; Sleep Disorder; Throat Irritation; Weight Decreased; Weight Increased; White Blood Cell Count Decreased			otherwise specified)	MI Most Recent Dose Was On 19/Jun/2014 Most Recent Rituxan Dose On 18/Jan/2	
	Naproxen	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown	Stopped Approx. Aug 2013	Not Reported
	Prednisone	S	Unknown	Stopped Approx. Jan 2013	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Actonel	S	Unknown		Not Reported
	Diphenhydramine Hcl	C	Oral		Not Reported
	Acetaminophen	C	Oral		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)		Not Reported
	Apo-Hydroxyquine	C			Not Reported
	Pms-Sulfasalazine	C			Not Reported
	Eltroxin	C			Not Reported
	Gabapentin	C			Not Reported
	Hydromorphone	C			Not Reported
	Lansoprazole	C			Not Reported
	Lorazepam	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	13952660	EXPEDITED (15-DAY)		OT	CA-ROCHE-1990184		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Fatigue; Groin Pain; Joint Noise; Joint Range Of Motion Decreased; Joint Stiffness; Middle Insomnia; Nonspecific Reaction; Pain In Extremity; Peripheral Swelling; Retinal Toxicity	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	13957945	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017756		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Nasopharyngitis; Neutropenia; Platelet Count Decreased; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Qd		Not Reported
	Xeljanz			S	Oral	5 Mg, Qd		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Advil /00044201/			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Ketorolac			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Methotrexate			C	Unknown	20 Mg, Q.Wk.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	14238407	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2017AP021637		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive;	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Indomethacin			S	Unknown	Unk		Not Reported

Arthralgia; Asthenia; Back Pain; Bone Density Abnormal; Contraindicated Product Administered; Crying; Decreased Appetite; Depression; Disability; Drug Ineffective; Fatigue; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Loss Of Personal Independence In Daily Activities; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure; Unevaluable Event; Vomiting	Prednisone	S	Oral	25 Mg, Qd	Apotex
	Prednisone	S	Oral	3 Mg, Qd	Apotex
	Prednisone	S	Oral	50 Mg, Unk	Apotex
	Apo-Leflunomide	S	Unknown	20 Mg, Qd	Apotex
	Apo-Prednisone	S	Oral	3 Mg, Qd	Apotex
	Apo-Prednisone	S	Oral	50 Mg, Qd	Apotex
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Oral	25 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Oral	25 Mg, Qd	Not Reported
	Methotrexate Sodium	S	Oral	25 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Unknown	20 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Unknown	12.5 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Oral	1 G, Bid	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Indocid /00003801/	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	30 Mg, Qd	Not Reported

	Cimzia	S	Subcutaneous	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Cymbalta	C	Oral	30 Mg, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Folic Acid	C	Oral	Unk, Q.Wk.	Not Reported
	Rituxan	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	14243135	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021933		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Osteoarthritis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Leflunomide			S	Unknown	10 Mg, Q.O.D.		Apotex
	Leflunomide			S	Unknown	5 Mg, Q.O.D.		Apotex
	Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Doxycycline			S	Unknown	50 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Unknown	0.8 Mg, Unk		Not Reported
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	15 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

Simponi	C	Subcutaneous	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Sulfasalazine	C	Unknown	Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	14804432	EXPEDITED (15-DAY)		OT	CA-ROCHE-2110773			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Tofacitinib Citrate			C				Not Reported
	Abatacept			C				Not Reported
	Leflunomide			C	Unknown	Therapy Duration: 549.0 Nos		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	15041745	EXPEDITED (15-DAY)		OT	CA-ROCHE-2142618		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	15260270	EXPEDITED (15-DAY)		HO	CA-ROCHE-2164477		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Prednisone	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Naproxen	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Methotrexate	C		Not Reported
	Folic Acid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	15411424	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186685		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Blood Creatinine Increased; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Knee Arthroplasty; Limb Discomfort; Musculoskeletal Discomfort; Pain; Pharyngeal Oedema; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Penicillin G [Benzylpenicillin]			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	15412513	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186027		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis; Toe Amputation	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Restasis			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	15417133	EXPEDITED (15-DAY)		OT	CA-ROCHE-2188024		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	15438204	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190752			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Use Issue; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	Dosage Form: Not Specified		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Cyclical		Not Reported
	Sulfasalazine			C	Unknown	Dosage Form: Not Specified		Not Reported
	Wellbutrin			C	Unknown			Not Reported

	Xeljanz	C	Unknown	Tablet Extended Release		Not Reported
	Bupropion	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	15751882	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20181226205		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Contraindicated Product Administered; Decreased Appetite; Drug Ineffective; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Headache; Hypersensitivity; Hypertension; Hypoaesthesia; Joint Swelling; Malaise; Mobility Decreased; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Simponi			S	Intravenous (not otherwise specified)			Janssen
	Stelara			S	Subcutaneous			Janssen
	Stelara			S				Janssen
	Reactine Unspecified (Cetirizine Dihydrochloride)			S	Unknown			Johnson And Johnson
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo Prednison			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S				Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

Fosamax	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Desoximetasone	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Otezla	S	Oral	Not Reported
Cetirizine Hydrochloride W/Pseudoephedrine Hy	S	Unknown	Not Reported
Topicort /00370301/	S	Unknown	Not Reported
Tofacitinib Citrate	S	Oral	Not Reported
Salazopyrine	C	Unknown	Not Reported
Diclofenac	C	Unknown	Not Reported
Methotrexate	C	Subcutaneous	Not Reported
Desoximetasone	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported
Dexamethasone	C	Unknown	Not Reported

	Acetaminophen W/Dextropropoxyphene	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	16387997	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-029784		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Hypersensitivity; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Celecoxib Capsules			S	Oral	200 Milligram, Once A Day		Aurobindo
	Levofloxacin Tablet			S	Unknown	Unk		Aurobindo
	Metronidazole			S	Intravenous (not otherwise specified)	5 Milligram		Aurobindo
	Pregabalin Capsules			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Ceclor			S	Unknown	Unk		Not Reported
	Cefaclor			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	200 Milligram, Once A Day		Not Reported
	Demerol			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	400 Milligram		Not Reported
	Leflunomide Sandoz			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Meperidine Hydrochloride			S	Unknown	Unk		Not Reported
	Meperidine Hydrochloride			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Every Week		Not Reported
	Norfloxacin			S	Unknown	400 Milligram		Not Reported
	Norfloxacin			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	400 Milligram, Once A Day		Not Reported

Prednisone	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	500 Milligram		Not Reported
Bisoprolol	S	Unknown	Unk		Not Reported
Erythro Base	S	Unknown	Unk		Not Reported
Act Diclo Miso	S	Unknown	Unk		Not Reported
Apo-Bisoprolol	S	Unknown	Unk		Not Reported
Apo-Leflunomide	S	Unknown	Unk		Not Reported
Apo-Prednisone	S	Unknown	Unk		Not Reported
Metronidazole	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17024875	EXPEDITED (15-DAY)		OT	CA-ROCHE-2461902			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17025673	EXPEDITED (15-DAY)		OT	CA-ROCHE-2460748			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Fluid	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Retention; Joint Swelling; Memory Impairment; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17088391	EXPEDITED (15-DAY)		DS	CA-ROCHE-2475266		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Ibuprofen			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apremilast			S	Unknown			Not Reported
	Apremilast			S	Unknown			Not Reported
	Apremilast			S				Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ibuprofen			S	Oral			Not Reported
	Infliximab			S	Oral			Not Reported

Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Motrin [Ibuprofen]	S	Oral	Not Reported
	Motrin [Ibuprofen]	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Otezla	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Endocervical	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C		Not Reported
	Colchicine	C	Oral	Not Reported
	Dexilant	C		Not Reported
	Febuxostat	C		Not Reported
	Folic Acid	C		Not Reported
	Gravol	C		Not Reported
	Mogadon	C	Oral	Not Reported
	Nitrazepam	C	Unknown	Not Reported
	Oxycodone	C		Not Reported
	Prednisone	C		Not Reported
	Uloric	C	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17235421	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508675		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Drug Ineffective; Infection; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arthrotec			C	Oral			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Gold			C	Unknown			Not Reported
	Imuran [Azathioprine]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17245567	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512065		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contraindicated Product Administered; Contusion; Drug Ineffective; Drug Intolerance; Fatigue;	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Treatment Failure; White Blood Cell Count Decreased	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17279295	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518789			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Bifidobacterium Bifidum			C	Unknown			Not Reported
	Loperamide			C	Oral			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17338159	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530847		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Advil [Ibuprofen]			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17358684	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533757			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Joint Swelling; Nausea; Nephrolithiasis;	Actemra			S	Intratumor			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Pneumonia; Pyelonephritis; Rash; Urosepsis	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17360983	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531687		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			C				Not Reported
	Prednisone			C	Unknown			Not Reported

	Rituxan			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17399434	EXPEDITED (15-DAY)		OT	CA-ROCHE-2539634		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Endodontic Procedure; Flushing; Heart Rate Decreased; Herpes Zoster; Ill-Defined Disorder; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Discolouration; Skin Disorder; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	8.0 Years		Not Reported
	Anakinra			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Ferrous Gluconate			C				Not Reported
	Folic Acid			C	Unknown			Not Reported
	Lasix [Furosemide]			C	Unknown			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Naprosyn [Naproxen]			C				Not Reported
	Oxycontin			C				Not Reported
	Oxyneo			C				Not Reported
	Diphenhydramine Hydrochloride			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17422945	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-010439		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Orencia			S	Subcutaneous	125 Milligram		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	20 Milligram		Not Reported
	Methotrexate			C	Subcutaneous	20 Milligram		Not Reported
	Neoral			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Neoral			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Rabeprazole Sodium			C	Oral	20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17423321	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542982		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis; Sensitivity To Weather Change; Toe Amputation	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Restasis			C	Unknown			Not Reported
	Synthroid			C				Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17465564	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-025776		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	10 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	22.5 Milligram	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qd	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram, Bid	Not Reported
	Prednisone	C	Oral	5 Milligram	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17682579	EXPEDITED (15-DAY)		DE, LT, OT	FR-ADVANZ PHARMA-202003002825			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Lung Assist Device Therapy; Off Label Use; Pneumonia; Pulmonary Embolism; Respiratory Failure	Hydroxychloroquine			S		600 Mg, Qd (Film-Coated Tablet)		Concordia
	Hydroxychloroquine			S		400 Mg, Qd (Film-Coated Tablet)		Concordia
	Amikacin			S	Intravenous (not otherwise specified)	2200 Mg, Qd		Not Reported
	Furosemide			C		Unk		Not Reported
	Retinol			C		Unk		Not Reported
	Cisatracurium			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Morphine			C		10 Mg		Not Reported
	Macrogol			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Amiodarone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17690932	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584270			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Contraindicated Product Administered; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17715901	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1228878		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Sudden Death	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Salbutamol (2297a)			S	Respiratory (inhalation)	0.1 Mg		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg, Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos		Not Reported
	Propofol (2373a)			S	Intravenous (not otherwise specified)			Not Reported
	Metoclopramida (1958a)			S	Intravenous (not otherwise specified)	10 Mg, Metoclopramida (1958a)		Not Reported
	Ipratropio Bromuro (1067br)			C	Respiratory (inhalation)	20 Mcg		Not Reported
	Enoxaparina Sodica (2482so)			C	Subcutaneous			Not Reported
	Cefotaxima (3840a)			C	Intravenous drip	4gram		Not Reported

Midazolam (2256a)	C	Intravenous drip	100 Mg		Not Reported
Tocilizumab (8289a)	C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17722969	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590358			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17743628	EXPEDITED (15-DAY)		CA	DE-UCBSA-2020017797			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Talipes	Certolizumab Pegol			S	Transplacental	Unknown Dose		Not Reported
	Prednisolone			S	Transplacental	Unknown Dose		Not Reported

	Hydroxychloroquine	S	Transplacental	Unknown Dose	Not Reported
	Sulfasalazine	S	Transplacental	Unknown Dose	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17753395	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-021940		54 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperkalaemia	Perindopril			S	Oral	Unk		Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17753415	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2020-021808		58 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase; Hypertransaminasaemia; Off Label Use	Piperacillin+Tazobactam			S	Intravenous (not otherwise specified)	1 Dosage Form, Once A Day		Aurobindo
	Kaletra			S	Oral	4 Dosage Form, Once A Day		Not Reported
	Plaquenil			S	Oral	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17753627	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-022319		49 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S				Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported
	Ceftriaxone			S				Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17753673	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-022323		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram, 1 Total		Not Reported
	Tocilizumab			S				Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17754072	EXPEDITED (15-DAY)		HO, LT	SI-TEVA-2020-SI-1233311		48 YR	Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Thrombocytopenia; Thrombocytopenia	Hydroxychloroquine Sulfate 200 Mg			S	Oral	200 Mg		Teva
	Kaletra (80 Mg + 20 Mg) / Ml			S	Oral	(80mg+20mg)/Ml Oral Solution, Dose 400mg/100 Mg, 1 Dosage Forms		Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Esmeron			C				Not Reported
	Metoclopramid			C				Not Reported
	Analgin			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17754345	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592877			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Product Use In	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported

Unapproved Indication	Lyrica		S	Oral	Not Reported
	Methotrexate		S	Oral	Not Reported
	Acetaminophen		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17754382	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004004842			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Thyroid Stimulating Hormone Decreased; Depersonalisation/Derealisation Disorder; Disturbance In Attention; Dyspnoea; Fatigue; Heart Rate Increased; Inflammation; Malaise; Somnolence; Weight Increased	Hydroxychloroquine			S		Unk		Concordia
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17754566	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593705			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Endocervical			Not Reported

Methotrexate	S	Subcutaneous	Not Reported
Methylprednisolone	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Naproxen	C	Unknown	Not Reported
Prednisone	C		Not Reported
Rituxan	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17754573	EXPEDITED (15-DAY)		DS	CA-ROCHE-2593227			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Contraindicated Product Administered; Foot Deformity; Loss Of Consciousness; Mobility Decreased	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Simponi		S	Subcutaneous	Not Reported
	Methotrexate		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17754642	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593253			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	92.0 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17754657	EXPEDITED (15-DAY)		HO	CA-ROCHE-2591253		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	944		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Ineffective; Drug Intolerance; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	365	Not Reported
	Rituxan	S	Intravenous drip		Not Reported
	Rituximab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported

	Sulfasalazine		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17754953	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593494			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17754966	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593515			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid	Actemra			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

Arthritis; Sciatica	Apo-Ramipril	S	Unknown		Not Reported
	Dorzolamide;Timolol	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Levothyroxine Sodium	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17754972	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010524			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Finger Deformity; Hand Deformity; Peripheral Swelling; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17754993	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1230791		47 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Paracetamol (12a)			S	Oral	3 Gram Daily;		Not Reported
	Dexketoprofeno (7312a)			S	Intravenous (not otherwise specified)	75 Milligram Daily;		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab (8289a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17755011	EXPEDITED (15-DAY)		DE	NVSC2020IR111441		9 YR	Male	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Fungal Infection	Hydroxychloroquine			S	Oral			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17755019	EXPEDITED (15-DAY)		OT	NVSC2020US121646		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cornea Verticillata	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	600 Mg, Bid		Novartis
	Everolimus			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17755052	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034382			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain;	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Paracetamol			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	25 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone			S	Oral	Unk		Not Reported

Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cortisone	S	Unknown	Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	20 Milligram, Qwk	Not Reported
	Folic Acid	S	Oral	5 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Golimumab	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Unk, Qd	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Qd	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Sarilumab	S	Unknown		Not Reported

Simponi	S	Subcutaneous	Unk		Not Reported
Stelara	S	Unknown			Not Reported
Sulfasalazine	S	Oral	1 Gram 2 Every 1 Day		Not Reported
Sulfasalazine	S	Unknown	500 Milligram		Not Reported
Sulfathalidine	S	Unknown			Not Reported
Topicort [Hydrocortisone Acetate]	S	Unknown	Unk		Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk		Not Reported
Xeljanz	S	Unknown	5 Milligram 2 Every 1 Day		Not Reported
Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C	Unknown			Not Reported
Salazopyrina	C	Unknown			Not Reported
Tofacitinib Citrate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17755116	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1230945		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400mg Day		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Azitromicina (7019a)			S	Oral	500mg Day		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Day		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab (8289a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17755117	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1231564		43 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatitis	Hidroxicloroquina (2143a)	S	Oral	400 Mg Day		Teva
	Hidroxicloroquina (2143a)	S				Teva
	Paracetamol (12a)	S	Oral	3 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17755120	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593218		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17755160	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592731		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug-Induced Liver Injury; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Therapy Duration: 6.0 Years		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17755184	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590945		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Pain; Spinal Compression Fracture; Treatment	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Failure	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17755361	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1231568		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400mg Daily		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Azitromicina (7019a)			S	Oral	500mg Daily		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Anakinra (2699a)			S	Subcutaneous	100 Mg		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600mg Daily		Not Reported
	Tocilizumab (8289a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17755393	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593389		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Aspirin [Acetylsalicylic Acid]	C		Not Reported
	Cymbalta	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17755414	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593685			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17755452	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593751		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Drug Ineffective; Synovitis;	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Treatment Failure	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17755505	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594111		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Rheumatoid Arthritis; Synovitis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)	84.0 Days		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	171.0 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17755896	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594375		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Infection; Insomnia; Loss Of Personal Independence In Daily Activities	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Rituximab		S	Intravenous drip	Solution Intravenous	Not Reported
	Sodium Aurothiomalate		S	Intramuscular		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756052	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020181655		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756057	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020181658		50 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accommodation Disorder; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756170	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202004003663			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Exfoliation	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756177	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1045121		21 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hepatitis; Hypocoagulable State; Pancreatitis Acute	Linezolid			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ambisome /00057501/			S	Intravenous (not otherwise specified)	Unk		Mylan
	Hidroxicloroquina /00072601/			S	Oral	400mg/24h		Mylan
	Tocilizumab			S	Intravenous (not otherwise specified)	Desconocida		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756292	EXPEDITED (15-DAY)		HO, LT, OT	FR-PFM-2020-13035			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Product Use Issue	Propranolol			S	Oral	20 Mg, Every 12 Hours		Pierre Fabre Medicament
	Laroxyl			S	Oral	15 Gtt Daily		Not Reported
	Plaquenil			S	Oral	400 Mg, Every 12 Hours		Not Reported
	Zithromax			S	Oral			Not Reported
	Paracetamol			C	Oral	Prn		Not Reported
	Pantoprazole			C	Oral	20 Mg Daily		Not Reported
	Oxygen			C	Respiratory (inhalation)	1 L Every Min		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756335	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591074			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Actemra			S	Unknown			Not Reported

Alopecia; Contraindicated Product Administered; Discomfort; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756579	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231653		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger Deformity; Limb Operation; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rocuronium			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756591	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231662		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger Deformity; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rocuronium Bromide	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756612	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592410		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Back Pain; Blood Pressure Increased; Bone Disorder; Contusion; Crying; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage; Hypersensitivity; Immune System Disorder; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Osteoarthritis; Pain; Pruritus; Rash; Spinal Disorder; Spinal Operation; Swelling; Therapy Non-Responder	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Therapy Duration: 198.0 Days		Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 156.0 Days		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756749	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593985			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756797	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2594249		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug	Rituxan			S	Intravenous (not			Not Reported

Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis			otherwise specified)			
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Bupropion	C				Not Reported
	Esomeprazole	C	Unknown	Not Specified		Not Reported
	Folic Acid	C	Unknown			Not Reported
	Levothyroxine Sodium	C				Not Reported
	Naproxen	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756818	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1045233		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	600 Milligram, Qd		Mylan
	Azithromycine Sandoz /00944304/			S	Oral	250 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756918	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592918			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Gabapentin	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756998	EXPEDITED (15-DAY)		LT	CA-BAUSCH-BL-2020-013031		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Minocycline Hydrochloride			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cannabis Sativa			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Oral			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Subcutaneous			Not Reported
	Ilaris Single-Use Vial			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported

Leflunomide	S	Oral	Not Reported
Leflunomide	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S		Not Reported
Oxycodone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Sodium Aurothiomalate	S		Not Reported
Salfasalazine	S	Unknown	Not Reported
Salfasalazine	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Lyrica	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757193	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593721		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Musculoskeletal Pain; Off Label Use; Pain	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 3.0 Months		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

In Extremity; Peripheral Swelling; Pharyngeal Oedema; Poor Quality Sleep; Pruritus; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome; Treatment Failure	Hydroxychloroquine		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Methotrexate		S	Oral	Therapy Duration: 4.0 Years	Not Reported
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Therapy Duration: 11.0 Months	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757227	EXPEDITED (15-DAY)		OT	ES-SA-2020SA118630		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg Day		Sanofi
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Sulpiride			S	Oral	50 Mg Every 8 Hours		Not Reported
	Enoxaparin Sodium			S	Subcutaneous	40 Mg Day		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757238	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1231627		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma	Alendronate Sodium			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr

Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Subcutaneous		Barr
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S			Not Reported
	Rituximab	S	Unknown	2000 Milligram Daily;	Not Reported
	Rituximab	S	Unknown	2000 Milligram Daily;	Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Alendronate	C	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757241	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231621		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	7.1429 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Adalimumab			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757245	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231635			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Rheumatoid Arthritis	Codeine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Barr
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757282	EXPEDITED (15-DAY)		OT	CA-SA-2020SA117632			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Desoximetasone			S	Oral			Sanofi
	Arava			S	Oral			Sanofi
	Cetirizine Hydrochloride			S				Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Folic Acid			S				Not Reported
	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Methotrexate			S	Oral			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Phthalylsulfathiazole		S	Intravenous (not otherwise specified)		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Tofacitinib Citrate		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757316	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231661			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Colectomy; Diarrhoea; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Speech Disorder Developmental; Treatment Failure; Treatment Failure	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757323	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232012			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Off Label Use;	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported

Rheumatoid Arthritis; Treatment Failure; Vomiting	Infliximab	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Morphine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757399	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1231650		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Alendronate			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown	2000 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757479	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231761			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Macular Degeneration; Pancreatitis	Prednisone			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757486	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232100		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass Excision; Nodule; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown			Barr
	Actonel			S	Oral			Not Reported
	Actonel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral	3.2143 Milligram Daily;		Not Reported
	Novo-Rythro			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Bupropion			C	Unknown			Not Reported

Cannabis Sativa	C	Unknown			Not Reported
Celebrex	C	Unknown	400 Milligram Daily;		Not Reported
Celebrex	C	Unknown			Not Reported
Ergocalciferol	C	Unknown			Not Reported
Ergocalciferol	C	Unknown			Not Reported
Hydroxychloroquine	C	Oral	400 Milligram Daily;		Not Reported
Wellbutrin	C	Unknown			Not Reported
Wellbutrin	C	Unknown	300 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757490	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232011		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Tuberculin Test Positive	Leflunomide			S	Oral	10 Mg		Barr
	Methotrexate			S	Unknown	5 Mg		Barr
	Cimzia Single-Use Prefilled Syringe			S	Unknown	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757559	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2020179134			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective For Unapproved Indication; Off Label Use	Azithromycin	S	Unk		Pfizer
	Azithromycin	S			Pfizer
	Hydroxychloroquine Sulfate	S	Unk		Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Morphine	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757730	EXPEDITED (15-DAY)		OT	IT-ABBVIE-20K-083-3395337-00		68 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Off Label Use	Kaletra			S	Oral			Not Reported
	Zitromax Avium			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Roactemra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757800	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3395439-00		41 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Off Label Use	Kaletra			S	Oral			Not Reported
	Zitromax Avium			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17757860	EXPEDITED (15-DAY)		OT	IT-ABBVIE-20K-083-3395468-00		70 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Off Label Use	Kaletra			S	Oral			Not Reported
	Zitromax Avium			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17758020	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231932			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Pantoprazole Magnesium			C				Not Reported
	Tenofovir Disoproxil Fumarate			C				Not Reported
	Xeljanz			C				Not Reported
	Zopiclone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17758024	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231959			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Gastrointestinal Disorder; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17758500	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594137		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Off Label Use; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	4.0 Years		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17758595	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593996		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17758709	EXPEDITED (15-DAY)		OT	CH-ABBVIE-20K-151-3392070-00		82 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use	Kaletra 200/50			S	Oral			Not Reported
	Kaletra 200/50			S	Oral			Not Reported
	Erythromycin			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Actemra			C	Intravenous drip			Not Reported
	Tazobac			C		2.0gr / 0.25mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17758863	EXPEDITED (15-DAY)		OT	RO-AUROBINDO-AUR-APL-2020-024107			Male	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Rupture; Off Label Use	Azithromycin			S	Unknown	Unk		Aurobindo
	Zinc			S	Unknown	Unk		Not Reported
	Vitamin C			S	Unknown	Unk		Not Reported
	Algozone			S	Unknown	Unk		Not Reported
	Norvir			S	Oral	Unk		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Lopinavir			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17759741	DIRECT	Y	DE			39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatine Phosphokinase Increased; Blood Fibrinogen Decreased; Blood Lactate Dehydrogenase Increased; Bundle Branch Block Right; Covid-19 Pneumonia; Dyspnoea; Electrocardiogram Qt Prolonged; Fibrin D Dimer Increased; Hypertension; Hypokalaemia; Hypoxia; Leukocytosis; Myocardial Infarction; Oedema Peripheral; Sars-Cov-2 Test Positive; Serum Ferritin Increased; Sinus Tachycardia	Hydroxychloroquine Sulfate Tablets	S	Oral	Teva
	Ceftriaxone	C		Not Reported
	Vancomycin	C		Not Reported
	Azithromycin	C		Not Reported
	Tocilizumab	C		Not Reported
	Piperacillin/Tazobactam	C		Not Reported
	Acetaminophen	C		Not Reported
	Albuterol	C		Not Reported
	Enoxaparin	C		Not Reported
	Ipratropium	C		Not Reported
	Losartan	C		Not Reported
	Oxymetazoline	C		Not Reported
	Kcl	C		Not Reported
	Propofol	C		Not Reported
	Norepinephrine	C		Not Reported
	Oseltamivir	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	11173619	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-1589861		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disability; Drug Ineffective; Dyspnoea; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Rash;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

Skin Mass; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapy Non-Responder; Therapy Non-Responder	Arava	S	Oral		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Cimzia	S	Unknown		Not Reported
	Cimzia	S	Unknown	Therapy Duration: 10.0 Month	Not Reported
	Cimzia	S	Unknown	Single Use Pre-Filled Syringe	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown	5-20 Mg As Necessary	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Apo-Hydroxyquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	11820435	EXPEDITED (15-DAY)		OT	CA-ROCHE-1675314		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis;	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Treatment Failure	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown	Does Not Tolerate 1 G Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	11999096	EXPEDITED (15-DAY)		DS	CA-ROCHE-1703918		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Disorder; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 5 Years		Not Reported
	Anakinra			S	Unknown	Therapy Duration: 5 Years		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 5 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 5 Years		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 5 Years		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 5 Years		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	12852770	EXPEDITED (15-DAY)		LT, OT	CA-ROCHE-1695185		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Infection;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Oral	4 Pills		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

Kidney Infection; Musculoskeletal Disorder; Rheumatoid Arthritis; Sepsis; Therapeutic Response Decreased	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	13015516	EXPEDITED (15-DAY)		OT	CA-ROCHE-1865715		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Joint Arthroplasty; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duratin: 6 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Gp2013			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

	Methotrexate	C	Unknown		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Leflunomide	C	Unknown	Therapy Duration: 6 Months	Not Reported
	Xeljanz	C	Oral		Not Reported
	Celebrex	C			Not Reported
	Diclofenac	C			Not Reported
	Lyrica	C			Not Reported
	Sulfasalazine	C			Not Reported
	Valsartan	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	13053281	EXPEDITED (15-DAY)		OT	CA-ROCHE-1870963			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Treatment Failure; Tremor	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

	Methotrexate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Zopiclone	C	Unknown	Not Reported
	Folic Acid	C	Oral	Not Reported
	Pantoprazole	C		Not Reported
	Tenofovir Disoproxil Fumarate	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Oral	Not Reported
	Tenofovir Disoproxil	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	13067695	EXPEDITED (15-DAY)		OT	CA-ROCHE-1870959			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Ineffective; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Nodule; Therapeutic Product Effect Decreased; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	13201712	EXPEDITED (15-DAY)		OT	CA-ROCHE-1889172			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis; Sensitivity To Weather Change; Toe Amputation	Rituxan			S	Intravenous drip			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C	Unknown			Not Reported
	Synthroid			C				Not Reported
	Restasis			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	13253859	EXPEDITED (15-DAY)		OT	CA-ROCHE-1894972		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Cimzia	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Humira	S	Unknown		Not Reported
Leflunomide	S	Unknown	Therapy Duration: 365.0 Nos	Not Reported
Methotrexate	S	Unknown	Therapy Duration: 19.0 Year(S)	Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown	Therapy Duration: 19.0 Years	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Therapy Duration: 2.0 Year(S)	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Unknown	Therapy Duration: 2.0 Year(S)	Not Reported
Gold	S	Unknown		Not Reported
Gold	S			Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown	Therapy Duration: 365.0	Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Parenteral		Not Reported
Prednisone	C	Unknown		Not Reported
Prednisone	C			Not Reported
Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	13262211	EXPEDITED (15-DAY)		OT	CA-ROCHE-1662402		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Actemra			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Anakinra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	13704441	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-1955227			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Solution	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Ilaris	S	Subcutaneous		Not Reported
	Ilaris	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S			Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S			Not Reported
	Marijuana	S	Unknown		Not Reported
	Minocycline	S	Unknown		Not Reported
	Minocycline Hydrochloride	S	Unknown		Not Reported
	Oxycodone	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine	S	Unknown		Not Reported

Sulfate]				
Sodium Aurothiomalate	S	Unknown		Not Reported
Sodium Aurothiomalate	S			Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S			Not Reported
Xeljanz	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	13868918	EXPEDITED (15-DAY)		OT	CA-ROCHE-1975064			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Cortisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	14678468	EXPEDITED (15-DAY)		OT	CA-ROCHE-2089917		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspepsia;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported

Hepatic Enzyme Increased; Hypertension; Pneumonia; Rheumatoid Arthritis	Azathioprine		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Leflunomide		S	Oral		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	14950745	EXPEDITED (15-DAY)		OT	CA-ROCHE-2131646		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Stomatitis	Rituximab			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 5 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported

	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	15275955	EXPEDITED (15-DAY)		OT	CA-ROCHE-2167429		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fatigue; Gastrointestinal Disorder; Hip Arthroplasty; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	15393834	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184304		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported

Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Risedronate Sodium	C		Not Reported
	Actonel	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	15438740	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190735			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Visual Impairment	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	15470422	EXPEDITED (15-DAY)		OT	US-JAZZ-2018-US-014635		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Fluctuation; Diarrhoea; Loss Of Consciousness; Malabsorption; Nausea; Osteoarthritis; Retching; Systemic Lupus Erythematosus; Vomiting; Weight Decreased	Xyrem			S	Oral	2.5 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustment		Jazz
	Xyrem			S	Oral	6 G, First Dose		Jazz
	Xyrem			S	Oral	6.5g, Second Dose		Jazz
	Xyrem			S	Oral	4.5 Gram First Dose		Jazz
	Xyrem			S	Oral	3.5 Gram Second Dose		Jazz
	Pilocarpine			S		Unknown		Not Reported
	Promethazine			S				Not Reported
	Hydroxychloroquine Phosphate			S				Not Reported
	Xifaxan			C		Unk		Not Reported
	Vitamin D3			C		Unk		Not Reported
	Linzess			C		Unk		Not Reported
	Zanaflex			C		Unk		Not Reported
	Cyclobenzaprine			C		Unk		Not Reported
	Zolpidem Tartrate			C		Unk		Not Reported
	Adderall			C		Unk		Not Reported
	Advair Hfa			C		Unk		Not Reported
	Allegra Allergy			C		Unk		Not Reported
	Metoprolol Tartrate			C		Unk		Not Reported
	Metoclopramide			C		Unk		Not Reported
	Rizatriptan			C		Unk		Not Reported
	Theophylline			C		Unk		Not Reported
	Biotin			C		Unk		Not Reported
	Cymbalta			C		Unk		Not Reported
	Maxalt Mlt			C		Unk		Not Reported

Prevacid	C	Unk	Not Reported
Requip	C	Unk	Not Reported
Singulair	C	Unk	Not Reported
Cyanocobalamin	C	Unk	Not Reported
Xarelto	C	Unk	Not Reported
Xopenex	C	Unk	Not Reported
Zinc Gluconate	C	Unk	Not Reported
Zyrtec	C	Unk	Not Reported
Advair	C	Unk	Not Reported
Ambien	C	Unk	Not Reported
Morphine Sulf	C	Unk	Not Reported
Tramadol Hcl	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	15944441	EXPEDITED (15-DAY)		HO, OT	US-SA-2019SA034910		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Coronary Artery Occlusion; Herpes Zoster; Mobility Decreased; Osteoporosis; Spinal Fracture	Clopidogrel Bisulfate			S	Unknown	Unk Unk, Unk		Sanofi
	Furosemide			S	Unknown			Sanofi
	Famotidine			S	Unknown	Unk Unk, Unk		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk Unk, Unk		Not Reported
	Doxycycline			S	Unknown	Unk Unk, Unk		Not Reported
	Trandolapril			S	Unknown	Unk Unk, Unk		Not Reported
	Prednisone			S	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Nifedipine			S	Unknown	Unk Unk, Unk		Not Reported
	Loperamide			S	Unknown	Unk Unk, Unk		Not Reported
	Ambien			S	Unknown	Unk Unk, Unk		Sanofi
	Gabapentin			S	Unknown	Unk Unk, Unk		Not Reported

	Esomeprazole Magnesium	S	Unknown	Unk Unk, Unk	Not Reported
	Rosuvastatin Calcium	S	Unknown	Unk Unk, Unk	Not Reported
	Potassium	S	Unknown	Unk Unk, Unk	Not Reported
	Glyceryl Trinitrate	S	Unknown	Unk Unk, Unk	Sanofi
	Metoclopramide Hydrochloride	S		Unk Unk, Unk	Not Reported
	Trazodone Hydrochloride	S		Unk Unk, Unk	Not Reported
	Isosorbide Mononitrate	S		Unk Unk, Unk	Not Reported
	Victoza	S	Unknown	Unk Unk, Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qod	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
	Humira	S			Not Reported
	Flomax [Morniflumate]	S	Unknown	Unk Unk, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	16451752	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019048692		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fall; Gastrointestinal Disorder; Interstitial Lung Disease; Liver Function Test Increased; Sepsis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S		Unk		Pfizer
	Pamidronate Disodium			S		Unk		Pfizer
	Xeljanz			S	Unknown	5 Milligram, Bid		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S				Pfizer
	Doxycycline			S	Unknown	Unk		Pfizer
	Doxycycline Hyclate			S	Unknown	Unk		Pfizer
	Stelara			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	6-Mercaptopurine Monohydrate			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported

Tenoxicam	S	Unknown	Unk		Not Reported
Bromocriptine	S		Unk		Not Reported
Ustekinumab	S	Unknown	Unk		Not Reported
Colchicine	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Azathioprine	S				Not Reported
Ciclosporin	S				Not Reported
Humira	S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
Leflunomide	S	Unknown	20 Mg, 1x/Day		Not Reported
Mercaptopurine	C				Not Reported
Methylprednisolone	C				Not Reported
Sulfasalazine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17024068	EXPEDITED (15-DAY)		OT	CA-ROCHE-2459889			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Therapeutic Response Decreased; Therapy Non-Responder	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17108802	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-063176			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue;	Diclofenac Sodium			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported

Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Actemra	S	Unknown	Not Specified	Not Reported
	Arava	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljan	S	Unknown		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Hydroxychloroquine Phosphate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17240218	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509529		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Feeding Disorder; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varenicline Tartrate			S	Oral			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C				Not Reported
	Acetaminophen;Oxycodone Hydrochloride			C	Oral			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Oral			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Oral			Not Reported
	Naproxen			C	Unknown			Not Reported

Naproxen	C	Oral		Not Reported
Naproxen	C	Oral		Not Reported
Oxycodone Hydrochloride	C			Not Reported
Rosuvastatin Calcium	C	Oral		Not Reported
Rosuvastatin Calcium	C	Oral		Not Reported
Valtrex	C	Oral		Not Reported
Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17244861	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510478		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pneumonia; Product Use In Unapproved Indication; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 411.0		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17245971	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512719			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphthous Ulcer; Drug Ineffective; Mouth Ulceration; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17259394	EXPEDITED (15-DAY)		HO	CA-ROCHE-2518182			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Pain; Nausea; Neck Pain; Pain; Pain In Extremity; Peripheral Swelling; Rash; Therapeutic Product Effect Decreased; Weight Decreased	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17260727	EXPEDITED (15-DAY)		OT	CA-ROCHE-2515953		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Synovitis; X-Ray Abnormal	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Penicillin-G			S	Unknown			Not Reported
	Penicillin G [Benzylpenicillin]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Calcium			C				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17411839	EXPEDITED (15-DAY)		DS	CA-ROCHE-2546716		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Enbrel	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Salazopyrin	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Gold	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Bifidobacterium Bifidum	C		Not Reported
	Celebrex	C		Not Reported
	Loperamide	C		Not Reported
	Pantoprazole	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17443400	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552179		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)	
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17484426	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559700		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Viral Upper Respiratory Tract Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17662183	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003002382			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Hallucination, Visual; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd, Film Coated Tablet		Concordia
	Temesta			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17663375	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-018165		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Ventricular Tachycardia	Azithromycin			S	Oral	250 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	Unk		Not Reported
	Lasilix			S	Intravenous (not otherwise specified)	2 Dosage Form, Once A Day		Not Reported
	Sufentanil			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Perfalgan			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Noradrenaline Tartrate Renaudin			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Midazolam			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Tazocilline			C	Intravenous (not otherwise specified)	4 Dosage Form, Once A Day		Not Reported
	Transipeg			C	Oral	Unk		Not Reported
	Potassium Chloride			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Nimbex			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Effexor			C	Oral	Unk		Not Reported
	Ultibro Breezhaler			C	Respiratory (inhalation)	Unk		Not Reported
	Seresta			C	Oral	Unk		Not Reported

	Rocephine			C	Intravenous (not otherwise specified)	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17670319	EXPEDITED (15-DAY)		DE	ES-FRESENIUS KABI-FK202003746		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Levofloxacin (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Azithromycin			S	Oral			Not Reported
	Ritonavir/Lopinavir			S	Oral			Not Reported
	Tacrolimus			S	Oral			Not Reported
	Enoxaparin Sodium			C	Subcutaneous			Not Reported
	Prednisone			C	Oral			Not Reported
	Ceftriaxone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17692715	EXPEDITED (15-DAY)		HO, OT	FR-ADVANZ PHARMA-202004002846			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pneumonia Bacterial; Pneumonia Bacterial; Staphylococcal Bacteraemia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	600 Mg, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		400 Mg, Qd		Concordia
	Cefotaxime Sodium			S	Intravenous (not otherwise specified)	6 G, Qd		Not Reported
	Cefotaxime Sodium			S	Intravenous (not otherwise specified)	6 G, Qd		Not Reported
	Spiramycin			S		6 Mu, Qd		Not Reported
	Vancomycine			S	Intravenous (not otherwise specified)	2 G, Qd		Not Reported
	Vancomycine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17707946	EXPEDITED (15-DAY)		DE, HO, OT	FR-ADVANZ PHARMA-202004003809			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Discomfort; Electrocardiogram Qt Prolonged; Loss Of Consciousness; Off Label Use; Ventricular Arrhythmia	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Azithromycin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17710765	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020055142		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis;	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S				Glaxosmithkline
	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S				Glaxosmithkline
	Pseudoephedrine Hcl			S	Unknown	Unk		Glaxosmithkline
	Desoximetasone			S	Oral	And Oral		Glaxosmithkline
	Topicort			S	Subcutaneous	Unk		Glaxosmithkline
	Topicort			S	Topical	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	5 Milligram		Glaxosmithkline
	Folic Acid			S	Oral	25 Milligram		Glaxosmithkline
	Cortisone Acetate			S	Unknown	25 Mg		Glaxosmithkline
	Cortisone Acetate			S	Unknown	25 Mg		Glaxosmithkline
	Cimzia (Certolizumab Pegol)			S	Subcutaneous	400 Milligram		Not Reported

Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Stelara	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	4 Milligram	Not Reported
	Humira	S		40 Milligram	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Once Daily (Qd)	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Sulfathalidine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	5 Milligram, 2x/Day (Bid)	Not Reported
	Xeljanz	S	Unknown	5 Milligram, 2x/Day (Bid)	Not Reported
	Xeljanz	S	Unknown	5 Milligram, 2x/Day (Bid)	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Once Daily (Qd)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	40 Milligram	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported

	Arava	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Salazopyrin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17717548	EXPEDITED (15-DAY)		OT	CA-ROCHE-2586707		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17721358	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588511			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Systemic Lupus Erythematosus	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17726275	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-020963		18 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Cholestatic Liver Injury; Diabetic Metabolic Decompensation;	Omeprazole			S	Intravenous (not otherwise specified)	20 Milligram, Once A Day		Aurobindo

Haemoglobin Decreased; Hepatocellular Injury; Infection; Inflammation; Pyrexia; Respiratory Disorder	Omeprazole	S	Intravenous (not otherwise specified)	40 Milligram, Once A Day	Aurobindo
	Hydroxychloroquine Sulfate	S	Unknown	1200 Milligram, Once A Day	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Once A Day	Not Reported
	Midazolam	S	Intravenous (not otherwise specified)	5 Dosage Form, Once A Day (5 Mg/Ml, Qd)	Not Reported
	Lovenox	S	Subcutaneous	0.6 Milliliter, Once A Day	Not Reported
	Loxen (Nicardipine Hydrochloride)	S	Intravenous (not otherwise specified)	30 Milligram, Once A Day	Not Reported
	Movicol	S	Unknown	2 Dosage Form (2 Df Bag)	Not Reported
	Diffu K	C	Unknown	3.6 Gram, Once A Day	Not Reported
	Diffu K	C			Not Reported
	Doliprane	C	Unknown	Unk	Not Reported
	Doliprane	C			Not Reported
	Paracetamol	C	Unknown	4 Gram, Once A Day	Not Reported
	Paracetamol	C			Not Reported
	Lasilix	C	Unknown	30 Milligram, Once A Day	Not Reported
	Novorapid	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17729385	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436819			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Deafness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17736281	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436855			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17744178	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436844			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Desoximetasone	C			Not Reported
	Plaquenil /00072602/	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17744179	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436805			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17744182	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200436802			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia;	Remicade			S	Intravenous (not otherwise specified)			Janssen

Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	C	Subcutaneous	Not Reported
	Arava	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17744192	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20200436812			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Disability; Drug Ineffective; Hepatic Enzyme Increased; Ileostomy; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Wheelchair User	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)		
	Plaquenil /00072602/	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17745328	EXPEDITED (15-DAY)			CH-PFIZER INC-2020175487		51 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Zithromax			S	Oral	500 Mg		Pfizer
	Piperacillin/Tazobactam			S	Intravenous drip	4.5 G		Pfizer
	Augmentin [Amoxicillin Sodium;Clavulanate Potassium]			S	Intravenous drip	1.2 G		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	800 Mg (In Total)		Not Reported
	Kaletra			S	Oral	400 Mg		Not Reported
	Kaletra			S	Oral	400 Mg		Not Reported
	Clexane			S	Subcutaneous	40 Mg		Not Reported
	Clexane			S	Subcutaneous	40 Mg		Not Reported
	Clexane			S	Subcutaneous	Unk		Not Reported
	Clexane			S	Subcutaneous	40 Mg		Not Reported
	Perfalgan			S	Intravenous (not otherwise specified)	1 Mg (Max 3x/Day ; As Necessary)		Not Reported
	Ipramol			C		Unk		Not Reported
	Temesta [Lorazepam]			C		Unk		Not Reported
	Tavanic			C		Unk		Not Reported
	Atracurium			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Dormicum [Midazolam Maleate]			C		Unk		Not Reported

Phosphate [Potassium Bicarbonate;Sodium Phosphate Monobasic]	C	Unk	Not Reported
Colistin	C	Unk	Not Reported
Torasemide	C	Unk	Not Reported
Potassium	C	Unk	Not Reported
Benerva	C	Unk	Not Reported
Heparin	C	Unk	Not Reported
Solu-Medrol	C	Unk	Not Reported
Novorapid	C	Unk	Not Reported
Relistor	C	Unk	Not Reported
Novasource Gi Control	C	Unk	Not Reported
Ventoline [Salbutamol]	C	Unk (As Necessary)	Not Reported
Movicol	C	Unk (As Necessary)	Not Reported
Tobramycin	C	Unk	Not Reported
Amphotericin B	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17747516	EXPEDITED (15-DAY)		OT	CA-SA-2020SA114923			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint	Cortisone Acetate			S		25 Mg		Not Reported
	Arava			S	Oral	20 Mg		Sanofi
	Cetirizine Hydrochloride			S		25 Mg		Not Reported
	Cetirizine Hydrochloride			S		10 Unk		Not Reported
	Folic Acid			S	Oral	5 Mg		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Hydrocortisone Acetate			S	Subcutaneous			Sanofi
	Methotrexate			S	Oral	Unk Unk, Qd		Not Reported

Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Methotrexate	S	Oral	25 Mg	Not Reported
	Methotrexate	S		Unk	Not Reported
	Leflunomide	S		Unk	Sanofi
	Pseudoephedrine Hydrochloride	S			Sanofi
	Sarilumab	S			Sanofi
	Sulfasalazine	S	Oral	1 Df, 1 Gram	Not Reported
	Sulfasalazine	S		500 Mg	Not Reported
	Desoximetasone	S	Oral	Unk	Sanofi
	Topicort	S	Subcutaneous		Sanofi
	Acetaminophen	S			Not Reported
	Actemra	S		Unk	Not Reported
	Apo-Prednisone	S			Not Reported
	Diclofenac Sodium	S		Unk	Not Reported
	Cortisone	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	20 Mg, Qw	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Golimumab	S			Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Methotrexate Sodium	S	Oral	25 Mg	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S		Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S		Unk	Not Reported
	Sulfathalidine	S			Not Reported
	Xeljanz	S		5 Mg, Bid	Not Reported

	Salazopyrina	C	Unk	Not Reported
	Tofacitinib Citrate	C	Unk	Not Reported
	Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17758660	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-20K-028-3390697-00		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Back Pain; Body Height Decreased; C-Reactive Protein Decreased; Deep Vein Thrombosis; Depression; Drug Ineffective; Drug Ineffective; Emotional Distress; Emotional Distress; Fatigue; Foot Fracture; Malaise; Osteoporosis; Pelvic Fracture; Pruritus Allergic; Psoriasis; Psoriatic Arthropathy; Quality Of Life Decreased; Rheumatoid Arthritis; Sensitivity To Weather Change; Spinal Fracture	Humira			S	Subcutaneous			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Methotrexate Sodium			C	Oral			Not Reported
	Warfarin			C				Not Reported
	Tofacitinib Citrate			C				Not Reported
	Vioxx			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17758765	EXPEDITED (15-DAY)		HO, OT	IT-ADVANZ PHARMA-202004004915			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Azithromycine			C		Unk		Not Reported

Heparin	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17758976	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594187		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759106	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2593615		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported

Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759129	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593284		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Finger Deformity; Joint Swelling; Laboratory Test Abnormal; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759190	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592797		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Osteoarthritis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Sulfasalazine			C				Not Reported
	Simponi			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759228	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594201		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759235	EXPEDITED (15-DAY)		OT	ES-SA-2020SA118599		45 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Enoxaparin Sodium			S	Subcutaneous	40 Mg, Qd		Sanofi
	Azithromycin			S	Oral	500 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759255	EXPEDITED (15-DAY)		HO	CA-ROCHE-2594261		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759262	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592749		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Drug Intolerance; Joint Swelling; Rheumatoid Factor Positive; X-Ray Abnormal	Actemra	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Diovan	C		Not Reported
	Docosahexaenoic Acid;Eicosapentaenoic Acid	C		Not Reported
	Sertraline	C	Unknown	Not Reported
	Valtrex	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759454	EXPEDITED (15-DAY)		DE, OT	MX-ADVANZ PHARMA-202004004823			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Haemodynamic Instability; Off Label Use; Renal Impairment	Hydroxychloroquine			S		200 Mg, Bid		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759495	EXPEDITED (15-DAY)		HO, OT	ALC2020CA003397			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness;	Phenylephrine			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg 1 Every 1 Months		Not Reported
	Arava			S	Unknown	20.0 Mg		Not Reported
	Benzalkonium Chloride			S	Unknown			Not Reported
	Benzalkonium Chloride;Diphenhydramine Hydrochloride;Phenylephrine Hydr			S	Unknown			Not Reported

Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Boric Acid	S	Unknown		Not Reported
	Cimzia	S	Unknown	Solution Subcutaneous (Single-Use Prefilled Syringe)	Not Reported
	Disodium Edetate	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	40.0 Mg 1 Every 1 Week	Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40.0 Mg	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200.0 Mg, Bid	Not Reported
	Methotrexate	S	Oral	15.0 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	C	Oral	5.0 Mg, Bid	Not Reported
	Rho D Immune Globulin	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Sodium Borate	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Tofacitinib Citrate	S	Unknown	10.0 Mg, Q2w	Not Reported
	Tofacitinib Citrate	S	Unknown	10.0 Mg, Q2w	Not Reported
	Tofacitinib Citrate	S	Subcutaneous	10.0 Mg, Q2w	Not Reported
	Prednisone	C	Unknown		Not Reported
	Celebrex	C	Oral	400.0 Mg	Not Reported
	Ibuprofen	C	Oral	400.0 Mg	Not Reported
	Lipitor	C	Oral	10 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759506	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594292			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759507	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594366			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759592	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592791			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hand Deformity; Impaired Work Ability; Joint Swelling; Polyarthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Indometacin			S	Oral			Not Reported
	Indometacin			S	Oral			Not Reported
	Indometacin			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Frequency: Cyclical		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Indomethacin [Indometacin]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759786	EXPEDITED (15-DAY)		HO, OT	IT-SA-2020SA115979		76 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Erythema; Rash Pustular	Clexane T			S	Subcutaneous	6000 Kiu, Qd		Sanofi
	Azithromycin			S	Oral	500 Mg, Qd		Not Reported
	Amlodipine Besilate			S	Oral	10 Mg, Qd		Not Reported
	Amlodipine Besilate			S	Oral	Unk (Dose Reduced)		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Sanofi
	Darunavir			S	Oral	800 Mg, Qd		Not Reported
	Ritonavir Sandoz			S	Oral	100 Mg, Qd		Not Reported
	Folifill			C				Not Reported
	Eutirox			C				Not Reported

	Ceftriaxone	C	1 Df, Qd		Not Reported
	Lasix [Furosemide]	C			Not Reported
	Urbason [Methylprednisolone]	C	Intravenous (not otherwise specified)	1 Df, Qd	Not Reported
	Omeprazole	C			Not Reported
	Trelegy Ellipta	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759880	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593767			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphthous Ulcer; Drug Ineffective; Intentional Product Use Issue; Mouth Ulceration; Off Label Use; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759960	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592727		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthropathy; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Knee Arthroplasty; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Musculoskeletal Disorder; Skin Warm; Spinal Stenosis; Therapeutic	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

Product Effect Decreased; Urinary Tract Infection			otherwise specified)	
	Simponi	S	Subcutaneous	Not Reported
	Gold	C		Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Prednisone	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17759962	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594885		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17760008	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594033			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined	Actemra			S	Subcutaneous			Not Reported

Disorder; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Off Label Use	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Anakinra	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17760032	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593250		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anticipatory Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis;	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

Synovitis			otherwise specified)		
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Acetaminophen	C			Not Reported
	Cetirizine Hydrochloride	C			Not Reported
	Desoximetasone	C			Not Reported
	Dexamethasone	C			Not Reported
	Gabapentin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17760116	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Measured Potency Issue; Therapy Non-Responder	Hydroxychloroquine Sulfate			S				Dr Reddys

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17760294	EXPEDITED (15-DAY)		HO, OT	ES-SA-2020SA116702		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Gastrointestinal Haemorrhage; Hepatitis Acute; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Enoxaparin Sodium			S	Subcutaneous	60 Mg, Q12h		Sanofi
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Mg, Qd For 6 Days Followed By 10 Mg Day X 5 Days		Not Reported
	Dexamethasone			S				Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Qd		Not Reported
	Azithromycin			S				Not Reported

	Tocilizumab	S	Intravenous (not otherwise specified)	600 Mg, 1x		Not Reported
	Tocilizumab	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17760385	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-02050		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cornea Verticillata; Off Label Use	Hydroxychloroquine			S	Unknown	600 Milligram, Bid		Lupin
	Hydroxychloroquine			S	Unknown	1200 Milligram (21.9 Mg/Kg) High Dose		Lupin
	Everolimus			C	Unknown	10 Milligram, Qd		Not Reported
	Everolimus			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17760413	EXPEDITED (15-DAY)		DE, OT	ES-VELOXIS PHARMACEUTICALS-2020VELES-000434		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Envarsus			S	Oral	Unk		Chiesi
	Lopinavir + Ritonavir			S	Oral	2 Df, Q12h		Not Reported
	Azitromicina			S	Oral	500 Milligram, Qd		Not Reported
	Hidroxicloroquina Sulfato			S	Oral	200 Milligram, Qd		Not Reported
	Levofloxacino [Levofloxacin]			S	Endocervical	Unk		Not Reported
	Prednisona			C	Oral	20 Milligram, Qd		Not Reported
	Ceftriaxona [Ceftriaxone]			C	Endocervical	Unk		Not Reported
	Enoxaparina Sodica			C	Subcutaneous	40 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17760655	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594303			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Drug Ineffective; Exposure During Pregnancy; Pain; Pemphigus; Systemic Lupus Erythematosus	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17760679	EXPEDITED (15-DAY)		OT	NVSC2020DE122948			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Off Label Use; Respiratory Tract Infection; Vomiting	Methotrexate			S	Unknown			Novartis
	Hydroxychloroquine			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Roactemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17760691	EXPEDITED (15-DAY)		DS	CA-ROCHE-2590101		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Indocid [Indometacin]			S	Unknown			Not Reported
	Indometacin			S	Unknown			Not Reported
	Indomethacin [Indometacin]			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Cymbalta			C	Oral			Not Reported

	Folic Acid	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17760787	EXPEDITED (15-DAY)		DE	IT-MYLANLABS-2020M1044962		70 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	400 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761059	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594942			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Simponi			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761128	EXPEDITED (15-DAY)		OT	SI-TEVA-2020-SI-1231758		50 YR	Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder	Hydroxychloroquine Sulphate Bp 200mg Tablet			S	Oral	200 Mg; 15.4. In The Evening And 16.4. In The		Teva

				Morning 400 Mg, Then 200 Mg/12 H	
	Daleron 500 Mg	S	Oral	500 Mg; As Necessary, Dotal Dose Of 2 Tbl On 14. And 15.4.	Not Reported
	Fragmin 5000 Ie	S	Subcutaneous	5000iu; 5000/24 Ur	Not Reported
	Pantoprazol Teva 20 Mg	C	Oral	20 Milligram Daily;	Not Reported
	Folkodin Alkaloid-Int	C	Oral	10 Mg; As Necessary 2caps/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761229	EXPEDITED (15-DAY)		HO	CA-ROCHE-2591156		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761316	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231938			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthma; Bursitis; Chronic Obstructive Pulmonary Disease; Drug Hypersensitivity; Gastrectomy; Hypothyroidism; Mammoplasty; Obesity; Osteoarthritis; Osteopenia; Phlebectomy; Synovitis; Therapeutic Product Effect Incomplete	Leflunomide	S	Unknown	20 Milligram Daily;	Barr
	Leflunomide	S	Unknown	10 Milligram Daily;	Barr
	Cosentyx	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	N-(3-Chloroallyl)Hexaminium Chloride	S	Unknown		Not Reported
	Penicillin G	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Stelara	S	Unknown		Not Reported
	Stelara	S	Unknown		Not Reported
	Cetirizine	C		20 Milligram Daily;	Not Reported
	Enbrel	C			Not Reported
	Lasix	C			Not Reported
	Montelukast	C		10 Milligram Daily;	Not Reported
	Synthroid	C		75 Microgram Daily;	Not Reported
	Terbutaline Sulfate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761320	EXPEDITED (15-DAY)		LT	FR-MYLANLABS-2020M1044981		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Venlafaxine			S	Oral	225 Milligram, Qd		Not Reported
	Plaquenil /00072602/			S	Oral	600 Milligram, Qd		Mylan
	Loxapine			S	Oral	155 Milligram, Qd		Mylan
	Theralene			S	Oral	50 Milligram, Qd		Mylan
	Paracetamol			C	Oral	1 Gram, Qd		Mylan
	Nicopatch			C	Transdermal	7 Milligram, Qd		Mylan
	Diazepam			C	Oral	10 Milligram, Qd		Mylan
	Atorvastatine /01326101/			C	Oral	40 Milligram, Qd		Mylan
	Nicotine			C	Oral	12 Milligram, Qd		Mylan

Macrogol 4000	C	Oral	Unk		Mylan
Nebivolol	C	Oral	7.5 Milligram, Qd		Mylan
Zopiclone	C	Oral	7.5 Milligram, Qd		Mylan
Ramipril	C	Oral	1.25 Milligram, Qd		Mylan
Akineton /00079502/	C	Oral	4 Milligram, Qminute		Mylan
Ezetimibe	C	Oral	10 Milligram, Qd		Mylan
Kardegic	C	Oral	75 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761340	EXPEDITED (15-DAY)		HO, OT	PT-ADVANZ PHARMA-GSH201712-006713			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Response Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Prednisolone			S	Unknown	15 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	25 Mg, Qd		Not Reported
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			C	Unknown	2 G, Qd		Not Reported
	Cyclophosphamide			C	Unknown	Unk		Not Reported
	Azathioprine			C	Intracardiac	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761350	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232520		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Prescribed Underdose	Naproxen			S	Unknown	1000 Milligram Daily;		Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Subcutaneous			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	1000 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761415	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1232499		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Naproxen			S	Unknown			Teva
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous	50 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral	2.6 Milligram Daily;		Not Reported
	Triamcinolone			S	Other			Not Reported
	Sulfasalazine			S	Oral	250 Milligram Daily;		Not Reported
	Triamcinolone Hexacetonide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761416	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1232985		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous	50 Milligram Daily;		Not Reported
	Anakinra			S	Unknown	50 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Immune Globulin (Human)			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral	2.6 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	250 Milligram Daily;		Not Reported
	Triamcinolone			S	Other			Not Reported
	Triamcinolone Hexacetonide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761468	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232206		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Laboratory Test Abnormal	Leflunomide	S	Unknown	20 Milligram Daily;	Barr
	Methotrexate	S	Unknown		Barr
	Actemra	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Hyzaar	C	Unknown		Not Reported
	Venlafaxine Hydrochloride	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761493	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2020-CA-1232500		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present; Gastroenteritis Viral; Human Anti-Human Antibody Test; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic	Naproxen			S	Unknown			Teva
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Oral	100 Milligram Daily;		Actavis
	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not			Not Reported

Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting			otherwise specified)		
	Adalimumab	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous	50 Milligram Daily;	Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Naproxen	S			Not Reported
	Apo-Prednisone	S	Oral	6 Milligram Daily;	Not Reported
	Apo-Prednisone	S	Oral	2.6 Milligram Daily;	Not Reported
	Apo-Prednisone	S	Oral	10 Milligram Daily;	Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Immune Globulin(Human)	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin(Human)	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin(Human)	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin(Human)	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported

Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Prednisone	S	Oral	2.6 Milligram Daily;	Not Reported
Prednisone	S	Oral	6 Milligram Daily;	Not Reported
Prednisone	S	Oral	2.6 Milligram Daily;	Not Reported
Sulfasalazine	S	Oral	250 Milligram Daily;	Not Reported
Sulfasalazine	S			Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Tocilizumab	S			Not Reported
Triamcinolone Acetonide	S	Unknown		Not Reported
Triamcinolone Acetonide	S	Unknown		Not Reported
Triamcinolone Acetonide	S	Intra-articular		Not Reported
Triamcinolone Hexacetonide	S	Other		Not Reported
Triamcinolone Hexacetonide	S	Unknown		Not Reported
Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761502	EXPEDITED (15-DAY)		HO, LT	ES-MYLANLABS-2020M1045105		62 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hepatitis; Long Qt Syndrome	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Azithromycin			S				Not Reported
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	2 Gr Dia		Mylan
	Ceftriaxona /00672201/			S				Mylan
	Dolquine			S	Oral	400 Mg Dia		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761537	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231771			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Certolizumab Pegol			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Advair			C				Not Reported
	Allopurinol			C				Not Reported
	Atrovent Hfa			C				Not Reported
	Codeine			C				Not Reported
	Cyclobenzaprine Hydrochloride			C				Not Reported
	Dilaudid			C				Not Reported
	Esomeprazole Magnesium Trihydrate			C				Not Reported
	Hydromorphone Hydrochloride			C				Not Reported

	Hydroxychloroquine Sulfate	C	Not Reported
	Ibuprofen	C	Not Reported
	Leucovorin Calcium	C	Not Reported
	Sulfasalazine	C	Not Reported
	Ventolin Hfa	C	Not Reported
	Xeljanz	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761541	EXPEDITED (15-DAY)		DE, OT	CA-TEVA-2020-CA-1231733		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sepsis; Synovitis; Terminal State; Thrombosis	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Doxycycline Hyclate			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Rituximab;Urelumab	C	Unknown	Not Reported
	Simponi	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761575	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1045111		53 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Propofol Infusion Syndrome	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Azithromycin			S				Not Reported
	Propofol			S	Intravenous (not otherwise specified)	Sedacion		Not Reported
	Dolquine			S	Oral	400 Mg Dia		Mylan
	Dolquine			S				Mylan
	Dexametasona /00016001/			C	Intravenous (not otherwise specified)	4 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761605	EXPEDITED (15-DAY)		LT, OT	CA-TEVA-2020-CA-1233076			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Meningitis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Visual Impairment	Naproxen Sodium			S	Unknown			Teva
	Indomethacin			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761786	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2020M1046273		39 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S	Unknown	10 Milligram, Qw		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Mylan
	Triamcinolone Acetonide			S		Intralesional Injection		Mylan
	Isoniazid			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17761846	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2020M1045048		17 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cryptococcosis; Hepatitis Toxic; Off Label Use	Methotrexate			S	Unknown	Unk		Not Reported
	Mabthera			S	Intravenous (not otherwise specified)	750 Milligram/Sq. Meter, Q2w		Mylan
	Prednisolone			S	Unknown	Unk		Mylan
	Prednisolone			S	Unknown	Unk		Mylan
	Prednisolone			S	Unknown	Unk		Mylan
	Cellcept /01275102/			S	Unknown	0.5 Gram, Qd		Mylan
	Cellcept /01275102/			S	Unknown	2 Gram, Qd		Mylan
	Methylprednisolone			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17762248	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1233084		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective	Naproxen			S	Unknown			Teva
	Methotrexate			S	Subcutaneous			Barr
	Metoprolol			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Apo-Metoprolol			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Naproxen Sodium			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17762464	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1232561		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Drug Hypersensitivity; Drug Ineffective; Dysbiosis; Fatigue; Infection; Inflammation; Insomnia; Maternal Exposure During Pregnancy; Nausea; Pain;	Naproxen			S	Unknown	1500 Milligram Daily;		Teva
	Naproxen			S		1500 Milligram Daily;		Teva
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Psoriasis; Rheumatoid Factor Positive; Synovitis; Thyroid Disorder	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Penicillin	S	Unknown	Not Reported
	Plaquenil	C		Not Reported
	Synthroid	C		Not Reported
	Tramadol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17762507	EXPEDITED (15-DAY)		HO	CA-ROCHE-2594982		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	7.0 Years		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17762702	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020185605		47 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis Acute; Off Label Use; Product Use In Unapproved Indication; Product Use Issue	Azithromycin			S	Oral	500 Mg, Daily		Pfizer
	Azithromycin			S				Pfizer
	Dexketoprofen			S	Intravenous (not otherwise specified)	25 Mg, Every 8 Hours		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Daily		Not Reported
	Hydroxychloroquine			S				Not Reported
	Tocilizumab			S	Intravenous (not	600 Mg, Single		Not Reported

				otherwise specified)			
	Tocilizumab		S				Not Reported
	Tocilizumab		S				Not Reported
	Paracetamol		S	Oral	1 G, Every 8 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17762783	EXPEDITED (15-DAY)		HO, LT, OT	JP-OSMOTICA_PHARMACEUTICAL_US_LLC-POI0573202000331		41 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Haemorrhage; Hormone Level Abnormal; Hypogonadism; Pelvic Infection; Placenta Accreta; Pre-Eclampsia; Proteinuria; Uterine Obstruction	Divigel			S	Transdermal	1.44 To 2.88 Mg Every 2 Days Each Between Fet 1 And Fet 4		Osmotica
	Divigel			S	Transdermal	1.44 Mg Every 2 Days During Fet 5		Osmotica
	Divigel			S	Oral	1.5 To 3.0 Mg Per Day During Fet 5		Osmotica
	Tacrolimus Monohydrate			S				Not Reported
	Progesterone			S	Vaginal			Not Reported
	Dydrogesterone			S	Oral			Not Reported
	Prednisolone			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17763134	EXPEDITED (15-DAY)		DE	CN-FRESENIUS KABI-FK202004535		37 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Histoplasmosis Disseminated; Respiratory Failure	Methylprednisolone (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Methylprednisolone (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Prednisone			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17763193	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232108		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Subcutaneous			Not Reported
	Actonel			S	Unknown			Not Reported
	Actonel			S	Unknown			Not Reported
	Actonel			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown	300 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

				otherwise specified)			
	Simponi		S	Subcutaneous			Not Reported
	Xeljanz		S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17763198	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1232213		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17763247	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594680		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Rituximab			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Elavil [Amitriptyline			S	Unknown			Not Reported

Hydrochloride]					
Folic Acid	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Infliximab	S	Unknown			Not Reported
Leflunomide	S	Unknown			Not Reported
Medroxyprogesterone Acetate	S	Unknown			Not Reported
Methotrexate	S	Unknown			Not Reported
Naprosyn [Naproxen]	S	Unknown			Not Reported
Oxycodone	S	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Etanercept	S	Unknown			Not Reported
Amitriptyline	S	Unknown			Not Reported
Cyclosporine	C				Not Reported
Depo Provera	C	Intramuscular	Sterile Aqueous Suspension		Not Reported
Kineret	C	Subcutaneous	100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17765180	DIRECT	Y	DE			58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sars-Cov-2 Test Positive	Hydroxychloroquine Sulfate Tablet			S	Oral			Actavis
	Lorazepam			C				Not Reported
	Morphine			C				Not Reported
	Sodium Chloride 0.9%			C				Not Reported
	Cefepime			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Zosyn			C				Not Reported

Azithromycin	C	Not Reported
Venofer	C	Not Reported
Kphos	C	Not Reported
D5w	C	Not Reported
1/2ns	C	Not Reported
Acetaminophen	C	Not Reported
Acetylcysteine	C	Not Reported
Ascorbic Acid	C	Not Reported
Bumetanide	C	Not Reported
Benadryl	C	Not Reported
Enoxaparin	C	Not Reported
Insulin Regular	C	Not Reported
Magnesium Hydroxide	C	Not Reported
Propofol	C	Not Reported
Reglan	C	Not Reported
Zofran	C	Not Reported
Versed	C	Not Reported
Protonix	C	Not Reported
Kayexalate	C	Not Reported
Zinc	C	Not Reported
Succinylcholine	C	Not Reported
Etomidate	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17765469	DIRECT	N	OT			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Humira Cf 40mg			S	Subcutaneous	Other Frequency:Once Every;		Abbvie
	Sulfasalazin			C				Not Reported
	Acyclovir			C				Not Reported
	Armour Thyro			C				Not Reported
	Gabapentin			C				Not Reported
	Hydroxychlor			S				Not Reported
	Pilocarpine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	11610346	EXPEDITED (15-DAY)		HO	CA-ROCHE-1643242		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Neoplasm; Decreased Immune Responsiveness; Immune System Disorder; Lyme Disease	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	13303877	EXPEDITED (15-DAY)		DS, HO, OT	CA-ROCHE-1902159		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disability; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme Increased; Ileostomy; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapy Non-Responder; Wheelchair User	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Phosphate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	15344061	EXPEDITED (15-DAY)		OT	CA-ROCHE-2177451		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Vaccine; Condition Aggravated; Diarrhoea; Drug Ineffective; Fall; Hypersensitivity; Laryngeal Disorder; Larynx Irritation; Nausea; Product Use Issue; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17240286	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514006		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bronchitis Chronic; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; General Symptom; Neck Pain; Off Label Use; Rheumatoid Factor Positive; Surgical Failure; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17287257	EXPEDITED (15-DAY)		HO	CA-ROCHE-2520375		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Hospitalisation; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Rheumatoid Arthritis; Secretion Discharge; Sputum Discoloured; Therapeutic Product Effect Decreased; Thrombosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Amitriptyline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17420209	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543007		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper;	Actemra			S	Unknown			Not Reported

Alopecia; Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	3 Years	Not Reported
	Humira	S	Subcutaneous	3 Months	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Infliximab	S	Unknown		Not Reported
	Methotrexate	S	Unknown	9.0 Years	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Gabapentin	C	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	C	Unknown		Not Reported
	Cetirizine Hydrochloride	C	Unknown		Not Reported
	Desoximetasone	C			Not Reported
	Dexamethasone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17655678	EXPEDITED (15-DAY)		DE, LT	FR-TEVA-2020-FR-1221608		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Ventricular Tachycardia	Azithromycine Anhydre			S	Oral	250 Milligram		Not Reported
	Lasilix 20 Mg/2 Ml, Solution			S	Intravenous (not	2 Dosage Forms		Not Reported

Injectable En Ampoule		otherwise specified)		
Plaquenil	S	Oral		Not Reported
Sufentanil	C	Intravenous (not otherwise specified)		Not Reported
Perfalgan 10 Mg/Ml, Solution Pour Perfusion	C	Intravenous (not otherwise specified)		Not Reported
Noradrenaline (Tartrate De)	C	Intravenous (not otherwise specified)		Not Reported
Midazolam	C	Intravenous (not otherwise specified)		Not Reported
Tazocilline 4 G/500 Mg, Poudre Pour Solution Pour Perfusion	C	Intravenous (not otherwise specified)	4 Dosage Forms	Not Reported
Transipeg	C	Oral		Not Reported
Potassium (Chlorure De)	C	Intravenous (not otherwise specified)		Not Reported
Nimbex	C	Intravenous (not otherwise specified)		Not Reported
Effexor L.P. 37,5 Mg, Gelule A Liberation Prolongee	C	Oral		Not Reported
Ultibro Breezhaler	C	Respiratory (inhalation)		Not Reported
Seresta 10 Mg, Comprime	C	Oral		Not Reported
Rocephine	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17705027	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202004003546			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury; Off Label Use; Pulmonary Embolism	Hydroxychloroquine			S		400 Mg, Qd (Film-Coated Tablet)		Concordia
	Paracetamol			C		Unk		Not Reported
	Rocephine			C		Unk		Not Reported

	Spiramycine	C	Unk	Not Reported
	Enoxaparin	C	Unk	Not Reported
	Dexamethasone	C	Unk	Not Reported
	Cefepime	C	Unk	Not Reported
	Cefazolin	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17760306	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1231595		49 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Off Label Use; Rash; Rash Maculo-Papular	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Teva
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Dosage Forms		Not Reported
	Lopinavir/Ritonavir			S	Oral	4 Dosage Forms		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17762677	EXPEDITED (15-DAY)		HO	CA-ROCHE-2594827			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Intravenous drip			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	Therapy Duration: 7.0 Years		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Enbrel	S	Subcutaneous	Not Reported
	Actemra	C	Subcutaneous	Not Reported
	Xeljanz	C		Not Reported
	Arava	C		Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17762926	EXPEDITED (15-DAY)		HO, LT, OT	JP-STRIDES ARCOLAB LIMITED-2020SP005498		41 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Disorder; Hormone Level Abnormal; Hypogonadism; Infarction; Maternal Exposure During Pregnancy; Off Label Use; Pelvic Infection; Placenta Accreta; Pre-Eclampsia; Proteinuria; Vaginal Haemorrhage	Tacrolimus			S	Unknown	4 Milligram		Strides
	Prednisolone			S	Unknown	7.5 Milligram		Not Reported
	Prednisolone			S	Unknown	Dose Increased		Not Reported
	Prednisolone			S	Unknown	7.5 Milligram		Not Reported
	Estradiol			S	Transdermal	Unk		Not Reported
	Progesterone			S	Vaginal	300 Milligram (Vaginal Tablet)		Not Reported
	Dydrogesterone			S	Oral	15 Milligram Per Day		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Oxytocin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763267	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594042		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Chills; Drug Ineffective; Drug Intolerance; Headache; Hepatic Enzyme Increased; Joint Swelling;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Desoximetasone			S	Unknown			Not Reported

Liver Disorder; Mesenteritis; Nausea; Oedema Peripheral; Off Label Use; Pyrexia	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763305	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592057		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Migraine; Nausea; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intracavernous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763308	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594865		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Stress	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	7.0 Months		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763309	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594899		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Gait Inability; Hypoaesthesia; Pharyngeal Oedema; Rash	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported

Enbrel	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763311	EXPEDITED (15-DAY)		DS	CA-ROCHE-2595012		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Naproxen			C	Unknown			Not Reported
	Levothyroxine Sodium			C	Unknown			Not Reported
	Bupropion			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763349	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1232236		83 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva

	Azitromicina (7019a)	S	Oral	500 Milligram Daily;	Not Reported
	Azitromicina (7019a)	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763356	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1232701		51 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763364	EXPEDITED (15-DAY)		OT	FR-ABBVIE-20K-056-3397056-00		68 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Right	Kaletra 200/50			S	Oral	Comprimé Pelliculé		Not Reported
	Plaquenil			S	Oral	200 Mg, Comprimé Enrobé		Not Reported
	Amlodipine			C				Not Reported
	Alprazolam			C				Not Reported
	Lovenox			C				Not Reported
	Paracetamol			C				Not Reported
	Candesartan Cilexetil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763369	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2020-ES-1232936		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia; Pancreatitis Acute	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported

Metilprednisolona (888a)	S	Intravenous (not otherwise specified)	250 Mg		Not Reported
Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid	S	Oral	2 Dosage Forms		Not Reported
Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	1 Gram		Not Reported
Tocilizumab (8289a)	S	Intravenous (not otherwise specified)	560 Mg		Not Reported
Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S	Oral	200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763370	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1232934		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Enoxaparina			S	Subcutaneous	40 Mg		Not Reported
	Enoxaparina			S	Subcutaneous	60 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763372	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594953			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Rituxan			S	Intravenous drip			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Arava	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763378	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594210		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Zostavax			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763390	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591044			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported

	Prednisone	C	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763394	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1232235		79 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Mg		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Colchicina / Dicloverina			S	Oral	1 Dosage Forms		Not Reported
	Colchicina / Dicloverina			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763429	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594157		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763436	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594901			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event; Rheumatoid Arthritis	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763447	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595032		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Breast Cancer; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763468	EXPEDITED (15-DAY)		OT	FR-ABBVIE-20K-056-3397060-00		92 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Electrocardiogram Qt Prolonged; Electrocardiogram U-Wave Prominent	Kaletra 200/50			S	Oral	Comprimé Pelliculé		Not Reported
	Kaletra			S	Oral	80 Mg/20 Mg, Solution Buvable		Not Reported
	Cordarone			S	Oral	200 Mg, Comprimé Sécable		Not Reported
	Plaquenil			S	Oral			Not Reported
	Xarelto			C				Not Reported
	Levothyrox			C				Not Reported
	Xatral			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763470	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1231930		56 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Hidroxicloroquina (2143a)			S	Oral	400mg		Teva
	Hidroxicloroquina (2143a)			S	Oral	2 Comp Cada 12 Horas El Primer Día Y Posteriormente 2 Comp		Teva

						Cada 24 H,				
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg				Not Reported
	Tocilizumab (8289a)			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763487	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1232707		73 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Completed Suicide	Hidroxicloroquina (2143a)			S	Oral	Loading Dose: 400 / 12h And Then 200mg / 12h Unit Dose :200 Milligram		Teva
	Metoclopramida (1958a)			C	Intravenous (not otherwise specified)	10 Milligram		Not Reported
	Metamizol (111a)			C	Intravenous (not otherwise specified)	2 Gram		Not Reported
	Paracetamol (12a)			C	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Ipratropio (1067a)			C	Oral	20 Microgram		Not Reported
	Ceftriaxona (501a)			C		2 Gram		Not Reported
	Beclometasona (463a)			C	Respiratory (inhalation)			Not Reported
	Furosemida (1615a)			C	Intravenous (not otherwise specified)	20 Milligram		Not Reported
	Azitromicina (7019a)			C	Oral	500 Mg On The First Day Unit Dose :250 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763509	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1232933		78 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Long Qt Syndrome	Azitromicina (7019a)			S	Unknown	Not Specified		Not Reported
	Propofol			S	Unknown			Not Reported

	Propofol	S			Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos	S	Oral	A Compressed Breakfast And Dinner 200 Milligram	Not Reported
	Midazolam (2256a)	S	Unknown		Not Reported
	Midazolam (2256a)	S			Not Reported
	Kaletra	S	Oral		Not Reported
	Ceftriaxona (501a)	S	Unknown	Not Specified	Not Reported
	Manidon Hta 240 Mg Comprimidos De Liberacion Prolongada, 30 Comprimido	C			Not Reported
	Rilast Turbuhaler 160 Microgramos/4,5 Microgramos/Inhalacion Polvo Pa	C			Not Reported
	Omnic Ocas 0,4 Mg Comprimidos De Liberacion Prolongada Recubiertos Con	C			Not Reported
	Simvastatina 20 Mg 28 Comprimidos	C			Not Reported
	Kalpress 160 Mg Comprimidos Recubiertos Con Pelicula, 28 Comprimidos (	C			Not Reported
	Cortic - Corticoide	C	Unknown	Low Dose Corticoids	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763514	EXPEDITED (15-DAY)		HO, LT	FR-TEVA-2020-FR-1232632		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Interaction; Electrocardiogram Qt Prolonged	Propranolol			S	Oral			Actavis
	Laroxyl 40 Mg/Ml, Solution Buvable			S	Oral	15 Gtt		Not Reported
	Zithromax 250 Mg, Comprime Pellicule			S	Oral	500 Milligram		Not Reported
	Plaquenil 200 Mg, Comprime Pellicule			S	Oral	400 Milligram		Not Reported
	Paracetamol			C	Oral	If Necessary		Not Reported
	Pantoprazole			C	Oral	20 Milligram		Not Reported

	Oxygene	C	Respiratory (inhalation)	1 Liters		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763517	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1232553		57 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab (8289a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763537	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1232935		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hyperbilirubinaemia	Amoxicilina / Acido Clavulanico			S	Intravenous (not otherwise specified)	1 Gr /8h		Teva
	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Enoxaparina (2482a)			S	Subcutaneous	80 Mg Day		Not Reported
	Ceftazidima (189a)			S	Intravenous (not otherwise specified)	2gr/8h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763552	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1232937		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Gastrointestinal	Azitromicina (7019a)			S	Intravenous (not otherwise specified)	500 Milligram Daily;		Not Reported

Haemorrhage; Hepatitis Acute	Azitromicina (7019a)	S				Not Reported
	Hidroxicloroquina (2143a)	S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)	S				Teva
	Enoxaparina (2482a)	S	Subcutaneous	120 Milligram Daily; Unit Dose: 60 Mg		Not Reported
	Tocilizumab (8289a)	S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab (8289a)	S				Not Reported
	Dexametasona (722a)	S	Intravenous (not otherwise specified)	20 Mg Day For 6 Days Followed By 10 Mg Day X 5 Days		Not Reported
	Dexametasona (722a)	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763555	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1232242		79 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763557	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1232550		64 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Levofloxacino (2791a)			S	Oral	500 Milligram Daily;		Teva
	Roactemra 20 Mg/Ml, Concentrado Para Solucion Para Perfusion			S	Intravenous (not otherwise specified)	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763558	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1232237		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763559	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1232931		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Cardio-Respiratory Arrest	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	4 Dosage Forms Daily; Unit Dose: 2 Df		Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17763644	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1232241		84 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Hidroxicloroquina (2143a)			S	Oral	400 Mg Loading Dose Followed By 200 Mg / Day, 200 Mg		Teva

	Azitromicina (7019a)	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2020	12958296	EXPEDITED (15-DAY)		OT	CA-ROCHE-1627311		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 6 Months		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	2 Doses		Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 12 Months		Not Reported
	Orencia			S	Unknown	Therapy Duration: 7 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 4 Months		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 9 Months		Not Reported
	Simponi			S	Subcutaneous	Therapy Duration: 3 Years		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2020	17721515	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589898			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cough; Drug Ineffective; Goitre; Headache; Inflammation; Joint Swelling; Knee Arthroplasty; Lower Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2020	17763679	EXPEDITED (15-DAY)		LT	FR-CADILA HEALTHCARE LIMITED-FR-ZYDUS-050282			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Risperidone			S	Oral	2 Milligram, Qd		Zydus Pharm
	Plaquenil Sulfate			S	Oral	600 Milligram, Qd		Not Reported
	Effexor			S	Oral	150 Milligram, Qd		Not Reported
	Acebutolol			C	Oral	400 Milligram		Not Reported
	Oxazepam			C	Oral	100 Milligram		Not Reported
	Enoxaparine Sodique			C	Subcutaneous	4000 International Unit		Not Reported
	Macrogol 4000			C	Oral	2 Dosage Form		Not Reported
	Amlodipine			C	Oral	10 Milligram		Not Reported

Zopiclone	C	Oral	7.5 Milligram		Not Reported
Nicardipine	C	Oral	60 Milligram		Not Reported
Hydrochlorothiazide	C	Oral	25 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2020	17763813	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595003		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Contraindicated Product Administered; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Rash; Syncope; Urticaria	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

	Prevacid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2020	17763889	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1233080			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dizziness; Drug Ineffective; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Naproxen			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Metoprolol			S	Unknown			Actavis
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Pms-Azithromycin			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2020	17763895	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1232981		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Naproxen Sodium			S	Unknown			Teva
	Prednisone Acetate			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Subcutaneous			Not Reported

	Leflunomide			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2020	17763913	EXPEDITED (15-DAY)		DS	CA-ROCHE-2594699		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	12470327	EXPEDITED (15-DAY)		OT	CA-ROCHE-1776829		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Gait Inability; Hypoaesthesia; Hypoaesthesia; Pharyngeal Oedema; Rash	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			C	Unknown	Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	13111555	EXPEDITED (15-DAY)		OT	CA-ROCHE-1878349		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Darifenacin			C				Not Reported
	Arava			C				Not Reported
	Ativan			C				Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			C				Not Reported
	Cortisone			C	Oral			Not Reported
	Dilaudid			C				Not Reported
	Darifenacin			C	Unknown			Not Reported
	Loperamide			C				Not Reported
	Norflex [Orphenadrine Citrate]			C				Not Reported
	Omnaris			C	Unknown			Not Reported
	Pantoprazole Sodium			C				Not Reported
	Plantago Ovata			C				Not Reported
	Synthroid			C				Not Reported
	Vagifem			C	Vaginal			Not Reported
	Diphenhydramine			C				Not Reported
	Pantoprazole Sodium			C				Not Reported
	Desoximetasone			C	Oral			Not Reported

	Furosemide		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	13116772	EXPEDITED (15-DAY)		OT	CA-ROCHE-1878330		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Chills; Drug Ineffective; Drug Intolerance; Headache; Hepatic Enzyme Increased; Joint Swelling; Liver Disorder; Mesenteritis; Nausea; Oedema Peripheral; Pyrexia	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Desoximetasone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	14222162	EXPEDITED (15-DAY)		OT	CA-ROCHE-2026226			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	14411605	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP005230		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Gait Inability; Joint Dislocation; Stomatitis	Diclofenac Sodium			S	Unknown	Unk		Apotex
	Desoximetasone			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	14682212	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2018M1017484			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apgar Score Low; Foetal Exposure During Pregnancy; Low Birth Weight Baby; Neonatal Respiratory Distress Syndrome; Premature Baby	Prednisone			S	Transplacental	25 Mg, Qd		Not Reported
	Prednisone			S	Transplacental	7.5 Mg, Qd		Not Reported
	Prednisone			S	Transplacental	10 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Transplacental	400 Mg, Qd		Not Reported
	Acetylsalicylic Acid			S	Transplacental	100 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	15263425	EXPEDITED (15-DAY)		OT	CA-ROCHE-2167406			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Rituxan			S	Intravenous (not otherwise specified)	Cyclical		Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported

Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Methotrexate Sodium	S	Subcutaneous	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Methotrexate Sodium	S	Intramuscular	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Intramuscular	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Intramuscular	Not Reported
Methotrexate	S	Unknown	Not Reported

Methotrexate	S	Subcutaneous	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	15408169	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20180908328		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Limb Deformity; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Indomethacin			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Actemra	S	Unknown	Not Reported
Radioactive Gold	S	Unknown	Not Reported
Indocid /00003801/	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Cymbalta	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	15458116	EXPEDITED (15-DAY)		OT	CA-ROCHE-2192139		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Hydroxychloroquine	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Leflunomide	S	Unknown			Not Reported
Sulfasalazine	C	Unknown			Not Reported
Wellbutrin	C	Unknown	Extended Release Tablet		Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	15741776	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20181218371		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchiectasis; Chest Pain; Disease Susceptibility; Drug Ineffective; Epicondylitis; Joint Swelling; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Toxicity To Various Agents; Upper Limb Fracture	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Simponi			S	Subcutaneous			Janssen
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S				Not Reported
	Procytox			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Neoral			S	Unknown			Not Reported

	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	16387989	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-029731			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Osteoarthritis; Pain; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Lisinopril Tablet			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Oral	Unk		Aurobindo
	Diclofenac Potassium			S	Oral	75 Milligram		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Every Week		Not Reported
	Plaquenil			S	Oral	200 Milligram, Once A Day		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Once A Day		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk, Two Times A Day		Not Reported
	Depo-Medrol			C	Intramuscular	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	16522648	EXPEDITED (15-DAY)		OT	CA-SA-2019SA177990			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Pain; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Sanofi
	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Oral	Unk Unk, Qw		Not Reported
	Myochrysine			S	Intramuscular	25 Mg, Qw		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Enbrel			S	Unknown	1000 Mg		Not Reported
	Orencia			S	Intravenous (not	Unk		Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	16524371	EXPEDITED (15-DAY)		OT	CA-SA-2019SA177768			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Hypoaesthesia	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Pregabalin			C	Oral	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	16530361	EXPEDITED (15-DAY)		OT	CA-SA-2019SA177463			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Pain; Rash; Squamous Cell Carcinoma; Treatment Failure	Hydroxychloroquine			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Citalopram Hydrobromide			C		40 Mg		Not Reported
	Prednisone			C		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17149990	EXPEDITED (15-DAY)		OT	FR-ACCORD-165350		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antinuclear Antibody Positive; Bicytopenia; Dermatitis Psoriasiform; Dna Antibody; Drug Ineffective; Evans Syndrome; General Physical Health Deterioration; Hypergammaglobulinaemia; Lymphadenopathy; Off Label Use; Pericarditis; Pyrexia; Scar; Skin Lesion; Subacute Cutaneous Lupus Erythematosus; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Accord
	Mycophenolic Acid			S				Accord
	Hydroxychloroquine			S				Not Reported
	Omeprazole			S				Not Reported
	Prednisone			S	Unknown			Not Reported
	Azathioprine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17195982	EXPEDITED (15-DAY)		OT	CA-ROCHE-2498563			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Simponi	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Pantoprazole Magnesium	C	Unknown		Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown		Not Reported
	Xeljanz	C			Not Reported
	Zopiclone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17246962	EXPEDITED (15-DAY)		HO	CA-ROCHE-2514284		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Nasonex			C	Unknown			Not Reported

	Prednisone	C	Unknown	Not Reported
	Trazodone	C	Unknown	Not Reported
	Zoledronic Acid	C	Unknown	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	Not Reported
	Trazodone Hydrochloride	C	Oral	Not Reported
	Tylenol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17310017	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527625		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17433987	EXPEDITED (15-DAY)		OT	CA-ROCHE-2551545		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17477145	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559556		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17683228	EXPEDITED (15-DAY)		DE, OT	FR-ADVANZ PHARMA-202004002752			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Shock	Hydroxychloroquine			S	Oral	600 Mg, Qd (Film-Coated Tablet)		Concordia
	Hydroxychloroquine			S	Oral	400 Mg, Qd (Film-Coated Tablet)		Concordia
	Cordarone			S	Intravenous (not otherwise specified)	600 Mg, Qd		Not Reported
	Cordarone			S	Intravenous (not otherwise specified)	900 Mg, Qd		Not Reported
	Noradrenaline			C		Unk		Not Reported
	Anaklnra			C		Unk		Not Reported
	Aspirina			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17685979	EXPEDITED (15-DAY)		HO, OT	US-ALEXION-A202005121		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Normocytic Anaemia; Off Label Use	Soliris 300mg			S	Intravenous (not otherwise specified)	900 Mg		Alexion
	Soliris 300mg			S	Intravenous (not otherwise specified)	900 Mg		Alexion
	Soliris 300mg			S	Intravenous (not otherwise specified)	900 Mg		Alexion
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Norepinephrine			C	Unknown	Unk		Not Reported
	Ceftriaxone			C	Unknown	2 Mg, Q12h		Not Reported
	Azithromycin			C	Unknown	Unk		Not Reported
	Rocephin			C	Unknown	Unk		Not Reported

	Propofol	C	Unknown	Unk		Not Reported
	Fentanyl	C	Unknown	Unk		Not Reported
	Midazolam	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17702366	EXPEDITED (15-DAY)		LT	FR-JNJFOC-20200420365		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Risperidone			S	Oral			Janssen
	Plaquenil			S	Oral			Not Reported
	Effexor			S	Oral			Not Reported
	Acebutolol			C	Oral			Not Reported
	Oxazepam			C	Oral			Not Reported
	Enoxaparine Sodique			C	Subcutaneous			Not Reported
	Macrogol 4000			C	Oral			Not Reported
	Amlodipine			C	Oral			Not Reported
	Clomipramine			C	Oral			Not Reported
	Zopiclone			C	Oral			Not Reported
	Nicardipine			C	Oral			Not Reported
	Hydrochlorothiazide			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17711495	EXPEDITED (15-DAY)		LT, OT	FR-ASTRAZENECA-2020SE54654		18 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Cholestatic Liver Injury; Diabetic Metabolic Decompensation; Haemoglobin Decreased; Infection; Inflammation; Pyrexia; Respiratory Disorder	Omeprazole			S	Intravenous (not otherwise specified)			Not Reported
	Omeprazole			S	Intravenous (not otherwise specified)			Not Reported
	Lovenox			S	Subcutaneous			Not Reported

Hydroxychloroquine Sulfate	S	Other		Not Reported
Hydroxychloroquine Sulfate	S	Other		Not Reported
Loxen (Loxoprofen Sodium)	S	Intravenous (not otherwise specified)		Not Reported
Movicol	S	Other	2 Df Bag	Not Reported
Midazolam	S	Intravenous (not otherwise specified)	5mg/Ml Daily	Not Reported
Paracetamol	C	Other		Not Reported
Paracetamol	C	Other		Not Reported
Doliprane	C	Unknown		Not Reported
Doliprane	C	Unknown		Not Reported
Lasilix	C	Other		Not Reported
Novorapid	C	Intravenous (not otherwise specified)	Unk	Not Reported
Diffu K	C	Other		Not Reported
Diffu K	C	Other		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17711760	EXPEDITED (15-DAY)		OT	DE-SA-2020SA095744		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Granuloma; Infective Tenosynovitis; Joint Swelling; Leukocytosis; Mycobacterium Marinum Infection; Pain In Extremity; Papule; Scab; Skin Mass; Thrombocytosis	Hydroxychloroquine			S	Oral	200 Mg, Q12h		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg, Qw		Not Reported
	Leflunomide			S	Oral	10 Mg, Qd		Sanofi
	Sulfasalazine			S	Oral	2 Df, Bid (500 Mg)		Not Reported
	Prednisolone			S	Oral	4 Mg, Qd		Not Reported
	Prednisolone			S	Oral	15 Mg, Qd		Not Reported
	Prednisolone			S	Oral	30 Mg, Qd		Not Reported
	Prednisolone			S	Oral	7.5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	20 Mg, Qd (Two Weeks Before Presentation)		Not Reported

Prednisolone	S	Oral	5 Mg, Qd		Not Reported
Prednisolone	S	Oral	40 Mg, Qd		Not Reported
Prednisolone	S	Oral	20 Mg, Qd		Not Reported
Prednisolone	S	Oral	10 Mg, Qd		Not Reported
Prednisone	S		Increased To		Not Reported
Prednisone	S		Unk		Not Reported
Amlodipine	C				Not Reported
Metoprolol	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17712397	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200432625		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Simponi			S	Subcutaneous			Janssen
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17712539	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP010162		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation; Choking; Condition Aggravated; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Ear Pain; Facial Pain; Facial	Folic Acid			S	Oral	5 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Prednisone			S	Oral	5 Mg, Qd		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Calcium Folinate			S	Oral	5 Mg, Qd		Not Reported

Paralysis; Fatigue; Fibromyalgia; Foot Deformity; Gait Disturbance; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Influenza Like Illness; Insomnia; Joint Range Of Motion Decreased; Lipoma; Melanocytic Naevus; Musculoskeletal Stiffness; Nasal Discomfort; Nasopharyngitis; Nausea; Night Sweats; Off Label Use; Oropharyngeal Discomfort; Osteoporosis; Pain; Pain In Extremity; Pain In Jaw; Pelvic Prolapse; Peripheral Coldness; Platelet Count Decreased; Post Procedural Infection; Rheumatoid Arthritis; Rhinorrhoea; Skin Mass; Therapeutic Product Effect Decreased; Throat Irritation	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	25 Mg, Unk	Not Reported
	Methotrexate	S	Oral	12.5 Mg, Q.Wk.	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Qd	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Acetaminophen	C	Oral	Unk	Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	C	Oral	Unk	Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Fentanyl	C	Unknown	1 Df, Unk	Not Reported
	Gabapentin	C	Oral	400 Mg, Bid	Not Reported
	Metformin Hydrochloride W/Sitagliptin	C	Oral	Unk, Bid	Not Reported
	Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
	Perindopril Erbumine	C	Oral	8 Mg, Qd	Not Reported
	Rabeprazole	C	Oral	180 Mg, Qd	Not Reported
	Ranitidine	C	Oral	150 Mg, Qd	Not Reported
	Rosuvastatin Calcium	C	Oral	5 Mg, Bid	Not Reported
	Sitagliptin	C	Oral	Unk, Bid	Not Reported
	Synthroid	C	Oral	1 Df, Qd	Not Reported
	Tylenol /00020001/	C	Unknown	Unk	Not Reported
	Vitamin B 12	C	Oral	1 Df, Qd	Not Reported
	Zopiclone	C	Oral	7.5 Mg, Qd	Not Reported
	Zostavax Ii	C	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17713381	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200431652			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Headache; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Stomatitis; Tinnitus	Simponi			S	Subcutaneous			Janssen
	Actemra			S				Not Reported
	Azathioprine			S				Not Reported
	Methotrexate			S				Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Sulfasalazine			S				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17718313	EXPEDITED (15-DAY)		HO, OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2020VAL000337			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia Bacterial; Pneumonia Bacterial; Staphylococcal Bacteraemia	Cefotaxime Sodium			S	Intravenous (not otherwise specified)	6 G, Qd		Validus
	Cefotaxime Sodium			S	Intravenous (not otherwise specified)	6 G, Qd		Validus
	Hydroxychloroquine Sulfate			S	Oral	600 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Not Reported
	Spiramycin			S	Nasal	6 Mu, Qd		Not Reported
	Vancomycin			S	Intravenous (not otherwise specified)	2 G, Qd		Not Reported
	Vancomycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17718785	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200431648		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Back Injury; Back Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Scoliosis; Spinal Disorder; Spinal Stenosis; Swelling; Therapeutic Response Decreased	Simponi	S	Subcutaneous	Janssen
	Actemra	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17728596	EXPEDITED (15-DAY)		OT	BE-ELI_LILLY_AND_COMPANY-BE202004006858		83 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Interaction; Electrocardiogram Qt Prolonged	Zyprexa Velotab 5mg			S	Oral	1/2 Tablet 2x/Day		Not Reported
	Zyprexa Velotab 5mg			S	Oral	1/2 Tablet 2x/Day		Not Reported
	Plaquenil S			S	Oral	1 Dosage Form, Bid		Not Reported
	Plaquenil S			S	Oral	1 Dosage Form, Daily		Not Reported
	Trazodone Eg			S	Oral	1/4 Tablet In Morning, At Noon, 1/2 Tablet In Evening,Patient Was Taking This Before Hospitalization		Not Reported
	Algostase Mono			C	Unknown			Not Reported
	Clexane			C				Not Reported
	Potassium 99			C	Oral	Unk, Unknown		Not Reported
	L-Thyroxine Roche			C	Unknown			Not Reported
	Perindopril			C	Unknown			Not Reported

Metformin	C	Unknown			Not Reported
Movicol Apelsin	C	Unknown			Not Reported
Prolopa	C	Unknown			Not Reported
Contramal	C	Unknown	1 Dosage Form, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17736942	EXPEDITED (15-DAY)		DS	CA-ROCHE-2589878		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Pregnancy; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

Humira	S	Subcutaneous		Not Reported
Fosamax	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Leflunomide	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 365.0	Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfathalidine	S	Oral		Not Reported
Sulfathalidine	S	Oral		Not Reported
Tofacitinib	S	Unknown		Not Reported
Tofacitinib Citrate	S	Unknown		Not Reported
Topicort [Desoximetasone]	S	Cutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Salazopyrin	C	Unknown		Not Reported

	Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17739711	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202004004131			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Renal Failure; Respiratory Distress	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd (Film-Coated Tablet)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17759142	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594369		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cortisone Acetate			C	Subcutaneous			Not Reported

	Desoximetasone	C		Not Reported
	Diclofenac	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17759175	EXPEDITED (15-DAY)		OT	CA-ROCHE-1698474		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Drug Ineffective; Fatigue; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Product Use Issue; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Incomplete; Therapy Non-Responder	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S				Not Reported
	Arava			S	Unknown	Therapy Duration 976.0		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown	Therapy Duration: 9 Years		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Therapy Duration: 10 Years		Not Reported
	Sulfasalazine			S	Oral	Therapy Duration 4 Years		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 9 Years		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17764083	EXPEDITED (15-DAY)		OT	BE-AUROBINDO-AUR-APL-2020-022169		83 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Olanzapine Orodispersible Tablets			S	Oral	1 Dosage Form, Once A Day,		Aurobindo
	Plaquenil			S	Oral	Day 1: 400mg 2x/D; Day 2-4:		Not Reported
	Trazodone Hydrochloride			S	Oral	1 Dosage Form, Once A Day,1/4		Not Reported
	Clexane			C	Endocervical	Unk		Not Reported
	Perindopril			C	Unknown	1 Dosage Form, Once A Day		Not Reported
	Movicol			C	Unknown	1 Dosage Form, Once A Day		Not Reported
	Levothyroxine			C	Unknown	1 Dosage Form, Once A Day		Not Reported
	Metformin			C	Unknown	2 Dosage Form, Once A Day		Not Reported
	Prolopa			C	Unknown	0.5 Dosage Form, Once A Day		Not Reported
	Contramal			C	Unknown	1 Dosage Form, As Necessary		Not Reported
	Kalium			C	Oral	Unk		Not Reported
	Algostase Mono			C	Unknown	3 Dosage Form, Once A Day		Not Reported
	Pradaxa			C	Unknown	Unk		Not Reported
	Uni Diamicron			C	Unknown	60 Milligram, Two Times A Day		Not Reported
	Magnetop			C	Oral	450 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17764121	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-246389		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Condition Aggravated; Hepatocellular Injury	Azithromycin			S	Oral	250 Milligram, Daily		Sun
	Plaquenil			S	Oral	600 Milligram, Daily		Not Reported
	Rocephine			S	Oral	2 Gram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17764172	EXPEDITED (15-DAY)		OT	IT-ADVANZ PHARMA-202004004910			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Disease Recurrence; Hypertension; Malaise; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17764183	EXPEDITED (15-DAY)		HO, OT	MX-ADVANZ PHARMA-202004004989			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Azithromycine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17764488	EXPEDITED (15-DAY)		HO, OT	FR-SA-2020SA119037		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Haematoma; Off Label Use; Purpura; Thrombocytopenia	Plaquenil	S	Oral	Unk		Sanofi
	Plaquenil	S				Sanofi
	Cefotaxime Sodium	S	Intravenous (not otherwise specified)	Unk		Sanofi
	Azithromycin	S	Oral	Unk		Not Reported
	Esomeprazole Magnesium	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Lovenox	S	Subcutaneous	Unk		Sanofi
	Noradrenaline [Norepinephrine]	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Nimbex [Cisatracurium Besilate]	C				Not Reported
	Loxen [Nicardipine Hydrochloride]	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sufentanil	C				Not Reported
	Hypnovel [Midazolam Hydrochloride]	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17764520	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597010		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lymphoma; Off Label Use	Rituximab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17764581	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593162			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Tenofovir Disoproxil Fumarate			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Zopiclone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17764632	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595750			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Minocycline Hydrochloride		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Xeljanz		S	Unknown	Not Reported
	Hydroxychloroquine		C	Unknown	Not Reported
	Leflunomide		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17764683	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594080			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased; Off Label Use	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17764919	EXPEDITED (15-DAY)		OT	ES-SAKK-2020SA118587AA		62 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg Dia		Sanofi
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Roactemra			S				Not Reported
	Enoxaparin Sodium			S	Subcutaneous	40 Mg Dia		Sanofi
	Ceftriaxone			S	Intravenous (not otherwise specified)	2gr Dia		Not Reported
	Azithromycin			S	Oral	500 Mg Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17764921	EXPEDITED (15-DAY)		OT	ES-SA-2020SA117856		53 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Azithromycin			S	Oral	500 Mg, Qd		Not Reported
	Enoxaparin Sodium			S	Subcutaneous	40 Mg		Sanofi
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17765001	EXPEDITED (15-DAY)		DE	ES-MYLANLABS-2020M1046051		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Sudden Death	Salbutamol			S	Respiratory (inhalation)	0.1 Milligram, Q6h		Not Reported
	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Metoclopramida /00041901/			S	Intravenous (not	10 Milligram, Q8h		Mylan

			otherwise specified)			
	Propofol	S	Intravenous (not otherwise specified)	Unk		Mylan
	Dolquine	S	Oral	400 Milligram, Bid		Mylan
	Ipratropio Bromuro	C	Respiratory (inhalation)	20 Microgram, Q6h		Mylan
	Enoxaparina Sodica	C	Subcutaneous	Unk		Mylan
	Cefotaxima /00497602/	C	Intravenous drip	4 Milligram, Bid		Mylan
	Midazolam	C	Intravenous drip	100 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17765075	EXPEDITED (15-DAY)		DE, OT	ES-ACCORD-181155		95 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Sudden Death	Quetiapine			S	Oral			Not Reported
	Levofloxacin/Levofloxacin Mesylate			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Risperidone			S	Oral			Not Reported
	Kaletra			S	Oral	200/50 Mg Film-Coated Tablets, 120 Tablets		Not Reported
	Losartan			C	Oral			Not Reported
	Clindamycin			C	Intravenous (not otherwise specified)			Not Reported
	Lorazepam			C	Oral			Not Reported
	Furosemide			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17765732	EXPEDITED (15-DAY)		OT	SI-PFIZER INC-2020185753		50 YR	Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Liver Disorder	Fragmin	S	Subcutaneous	5000 Iu / 24 Hours	Pfizer
	Hydroxychloroquine Sulphate	S	Oral	On 15apr In The Evening And On 16apr In The Morning With Dose Of 400 Mg, Then 200 Mg/12 H	Not Reported
	Hydroxychloroquine Sulphate	S	Oral	400 Mg In The Evening	Not Reported
	Hydroxychloroquine Sulphate	S	Oral	400 Mg In The Morning	Not Reported
	Daleron	S	Oral	500 Mg; As Necessary, Total Dose Of 2 Tbl On 14apr And 15apr	Not Reported
	Pantoprazol Teva	C	Oral	20 Mg; 20 Mg/Day	Not Reported
	Folkodin Alkaloid	C	Oral	10 Mg; As Necessary 2caps/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17765761	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595576			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported
	Simponi			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17765939	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594074			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Off Label Use; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tiaprofenic Acid			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17765964	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592191		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Astigmatism; Contraindicated Product Administered; Drug Ineffective For Unapproved Indication;	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported

Dyspnoea; Hypersensitivity; Impaired Work Ability; Pain; Paraesthesia; Swelling; Therapeutic Product Effect Decreased; Vomiting	Cimzia		S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Naproxen		S	Oral		Not Reported
	Orencia		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Baclofen		S	Unknown		Not Reported
	Baclofen		S	Unknown		Not Reported
	Sulfadiazine		S	Unknown		Not Reported
	Xeljanz		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17766014	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593237			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17766223	EXPEDITED (15-DAY)		DS	CA-ROCHE-2596648		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17766384	EXPEDITED (15-DAY)		OT	FR-ACCORD-181003		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin Sandoz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17766429	DIRECT	Y	OT			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Interaction; Hypoglycaemia	Hydroxychloroquine			S	Oral			Not Reported
	Glimeperide			C				Not Reported
	Cyclosporine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17766484	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020185527		69 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperkalaemia; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	Unk		Pfizer
	Cefotaxime			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Telmisartan			S	Oral	40 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17766486	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020185579		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg, 1x/Day (500 Mg Day)		Pfizer
	Azithromycin			S				Pfizer
	Metamizole			S	Intravenous (not otherwise specified)	2 G, 4x/Day (2 G Every 6 Hours)		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day (400 Mg/Day)		Not Reported
	Paracetamol			S	Intravenous (not otherwise specified)	1 G, 3x/Day (1g Every 8 Hours)		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17766918	EXPEDITED (15-DAY)		HO	CA-SA-2020SA118445		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Plaquenil			S		Unk		Sanofi
	Arava			S				Sanofi
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Cortisone			S		10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17766966	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-15268			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anaphylactic Shock; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nausea; Renal Impairment; Synovitis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Cosentyx			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Otezla			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17767571	EXPEDITED (15-DAY)		HO	IN-MYLANLABS-2020M1046274		29 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphagia; Toxic Epidermal Necrolysis	Hydroxychloroquine			S	Unknown	100 Milligram Bid, Had Been Receiving For 2 Months		Not Reported
	Prednisolone			C	Unknown	30 Milligram, Qd		Mylan
	Prednisolone			C	Unknown	60 Milligram, Qd		Mylan
	Mycophenolate Mofetil			C	Unknown	1.5 Gram, 0.5 Day		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17767604	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020185539		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal;	Zithromax			S	Oral	750 Mg, 1x/Day		Pfizer

Nausea; Off Label Use; Product Use In Unapproved Indication	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	600 Mg, 1x/Day		Not Reported
	Rocephine	C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17767609	EXPEDITED (15-DAY)		DE	FR-MYLANLABS-2020M1045896			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Intentional Product Misuse; Off Label Use	Azithromycin			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17767962	EXPEDITED (15-DAY)		HO	ES-BAUSCH-BL-2020-013311		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Gastrointestinal Haemorrhage; Hepatitis Acute	Dexametasona			S	Intravenous (not otherwise specified)	20 Mg Day For 6 Days Followed By 10 Mg Day X 5 Days		Bausch And Lomb
	Dexametasona			S				Bausch And Lomb
	Hidroxicloroquina			S	Oral			Not Reported
	Hidroxicloroquina			S				Not Reported
	Enoxaparina			S	Subcutaneous			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	Total		Not Reported
	Tocilizumab			S				Not Reported
	Azitromicina			S	Intravenous (not otherwise specified)			Not Reported
	Azitromicina			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17768202	EXPEDITED (15-DAY)		OT	US-EMERGENT BIOSOLUTIONS-20000341SP			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Rheumatoid Arthritis	Narcan			S	Unknown	4 Milligram		Emergent Biosolutions
	Prednisone			S	Unknown			Not Reported
	Wellbutrin			S	Unknown	300 Milligram, Qd		Not Reported
	Wellbutrin			S	Unknown	150 Milligram, Qd		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Cyclobenzaprine Hcl			S	Unknown	Unk		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17768204	EXPEDITED (15-DAY)		OT	US-EMERGENT BIOSOLUTIONS CANADA INC.-20000340SP		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Narcan			S	Unknown	4 Milligram		Emergent Biosolutions
	Plaquenil			S	Unknown	Unk		Not Reported
	Wellbutrin			S	Unknown	150 Milligram, Qd		Not Reported
	Wellbutrin			S	Unknown	300 Milligram, Qd		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily; 60/Btl		Not Reported
	Cyclobenzaprine Hcl			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	9459293	EXPEDITED (15-DAY)		OT	CA-ROCHE-1162770		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Diastolic Increased; Blood Pressure Fluctuation;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not			Not Reported

Blood Pressure Increased; Blood Pressure Systolic Abnormal; Blood Pressure Systolic Increased; Cataract; Cystitis; Drug Intolerance; Dry Mouth; Dyslipidaemia; Fall; Hepatic Enzyme Increased; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Nasopharyngitis; Osteoporosis; Painful Respiration; Pharyngeal Mass; Pneumonia; Poor Venous Access; Synovitis; Upper Limb Fracture; Weight Increased			otherwise specified)		
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Synthroid	C			Not Reported
	Flexeril [Cyclobenzaprine Hydrochloride]	C			Not Reported
	Vitamin B Complex	C			Not Reported
	Tylenol	C			Not Reported
	Folic Acid	C			Not Reported
	Garlic [Allium Sativum]	C			Not Reported
	Methotrexate	C	Unknown		Not Reported
	Sulfasalazine	C	Oral		Not Reported
	Naprosyn [Naproxen]	C			Not Reported
	Calcium	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	10296970	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1105839		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthritis; Blood Creatinine Decreased; Condition Aggravated;	Rituxan			S	Intravenous (not otherwise specified)	First Rpap Dose		Not Reported

Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Discharge; Eye Disorder; Eye Operation; Eye Pain; Fatigue; Glaucoma; Haematocrit Decreased; Haemoglobin Decreased; Headache; Inflammation; Lacrimation Increased; Lymphocyte Count Increased; Monocyte Count Increased; Nasopharyngitis; Nausea; Neutrophil Count Decreased; Ocular Procedural Complication; Optic Neuritis; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Tinnitus; Vision Blurred; White Blood Cell Count Decreased	Rituxan	S	Intravenous (not otherwise specified)	Unknown Dosing Details	Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Folic Acid	S	Unknown	Once Daily Except Friday	Not Reported
	Folic Acid	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Discontinued Due To Ophthalmic Problems	Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Dilaudid	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Acetaminophen	S	Oral		Not Reported
	Acetaminophen	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Apo-Acetaminophen	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Fosavance	C	Unknown		Not Reported
	Hyzaar	C	Unknown		Not Reported
	Hyzaar	C	Unknown		Not Reported
	Diphenhydramine Hcl	C	Oral		Not Reported
	Diphenhydramine Hcl	C	Unknown		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)		Not Reported
	Hydrocortisone	C	Intravenous (not otherwise specified)		Not Reported
	Humira	C			Not Reported

	Orencia	C	Not Reported
	Remicade	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	12248361	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1737509		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Dysphonia; Gait Disturbance; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Spinal Operation; Sputum Discoloured; Thrombosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Warfarin			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Warfarin			S	Unknown			Not Reported
	Amitriptyline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	13059040	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015749		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Drug	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Apo-Leflunomide			S	Oral	10 Unk, Unk		Apotex

Ineffective; Drug Interaction; Hepatotoxicity; Joint Swelling; Nausea; Neoplasm Malignant; Off Label Use; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Apo-Prednisone	S	Unknown	Unk	Apotex
	Leflunomide	S	Unknown	20 Mg, Unk	Apotex
	Leflunomide	S	Oral	10 Mg, Unk	Apotex
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S			Not Reported
	Hydroxychloroquine	S	Unknown	300 Mg, Unk	Apotex
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazin	S	Unknown	2 G, Unk	Not Reported
	Sulfasalazin	S	Unknown	2 Mg, Unk	Not Reported
	Sulfasalazin	S	Unknown	500 Mg, Unk	Not Reported
	Arava	S	Unknown	10 Mg, Unk	Not Reported
	Arava	S	Unknown	20 Mg, Unk	Not Reported
	Celebrex	S	Unknown	50 Mg, Q.Wk.	Not Reported
	Celebrex	S			Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
	Enbrel	S	Unknown	50 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	2.5 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Unk	Not Reported
	Orencia	S	Subcutaneous	250 Mg, Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	300 Mg, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	2 G, Unk	Not Reported
	Sulfasalazine	S	Unknown	2 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	13224700	EXPEDITED (15-DAY)		OT	CA-ROCHE-1890670			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Hip Arthroplasty; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	10/--/1997 To 02/--/1999, Duration- 2 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Sodium Aurothiomalate			C				Not Reported
	Arava			C	Unknown			Not Reported
	Leflunomide			C	Unknown	Duration- 11 Years		Not Reported
	Actemra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	13625046	EXPEDITED (15-DAY)		OT	CA-HORIZON-VIM-0072-2017		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Antinuclear Antibody Positive; Arthralgia; Atelectasis; Bursitis; Conjunctivitis; Contraindicated Product Administered; Crepitations; Cushingoid; Drug Ineffective; Dry Eye;	Vimovo			S	Oral	Unknown Dose		Not Reported
	Methotrexate			S	Oral	20 Mg Weekly, Restarted 2008		Not Reported
	Naproxen			S	Oral	500 Mg Bid, 250 Mg Bid, 1000 Mg Bid		Not Reported
	Enbrel			S	Subcutaneous	50 Mg Once Weekly		Not Reported

Dry Mouth; Dyspnoea; Erythema; Eye Irritation; Eye Pain; Feeling Jittery; Fibromyalgia; Flank Pain; Haemoglobin Decreased; Impaired Work Ability; Infection; Interstitial Lung Disease; Joint Effusion; Joint Swelling; Lung Disorder; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neoplasm Malignant; Nodule; Ocular Hyperaemia; Pain; Pain In Extremity; Peripheral Swelling; Photophobia; Pleuritic Pain; Pneumonia; Pruritus; Rash; Red Blood Cell Count Decreased; Rheumatoid Arthritis; Rheumatoid Nodule; Scleritis; Swelling Face; Synovial Cyst; Synovial Fluid Analysis; Tenderness; Tenosynovitis Stenosans; Therapeutic Product Effect Decreased; Thrombosis; Ulcer; Visual Impairment; Wheezing	Pantoloc	S	Oral	Daily	Not Reported
	Alendronic Acid	S	Oral		Not Reported
	Amitriptyline Hydrochloride	S	Oral	75 Mg Daily	Not Reported
	Depo Medrol	S	Intra-articular		Not Reported
	Humira	S	Subcutaneous	40 Mg Unknown, Solution For Injection	Not Reported
	Imuran	S		150 Mg	Not Reported
	Lyrica	S	Oral	300 Mg Qd, 150 Mg Bid	Not Reported
	Meloxicam	S		150 Mg Daily	Not Reported
	Prednisone	S		15 Mg Qd	Not Reported
	Ranitidine	S	Oral	300 Mg Qd	Not Reported
	Ratio-Oxycocet	S			Not Reported
	Septra	S			Not Reported
	Sulfasalazine	S	Oral	1 G, Daily	Not Reported
	Tofacitinib	S	Oral	5 Mg Bid And 10 Mg Daily	Not Reported
	Folic Acid	C			Not Reported
	Plaquenil	C			Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Apo-Amitriptyline	S	Oral	75 Mg Qd	Not Reported
	Apo-Meloxicam	S			Not Reported
	Apo-Naproxen	S	Oral	500 Mg Bid	Not Reported
	Apo-Prednisone	S		15 Mg Daily	Not Reported
	Apo-Ranitidine	S	Oral	150 Mg Bid	Not Reported
	Teva-Oxycocet	S			Not Reported
	Apo-Alendronate	S			Not Reported
	Bactrim	S			Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	S			Not Reported
	Esomeprazole Magnesium	S	Oral		Not Reported
	Ranitidine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Tofacitinib	S	Oral	5 Mg Two Times Daily	Not Reported
	Celebrex	C			Not Reported

Celebrex	C			Not Reported
Eltroxin	C			Not Reported
Dexilant	C			Not Reported
Codeine	C	Qd		Not Reported
Cimzia	C			Not Reported
Cannabis Sativa	C			Not Reported
Orencia	C	Unknown		Not Reported
Pantoprazole	S			Not Reported
Alendronate Sodium	S	Unknown		Not Reported
Amoxicillin	S	Unknown		Not Reported
Mobicox	S			Not Reported
Pregabalin	S	Oral		Not Reported
Azathioprine	S			Not Reported
Hydroxychloroquine Phosphate	S			Not Reported
Elavil	S			Not Reported
Adalimumab	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	13975158	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018001			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	640 Mg, Q.Wk.		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	400 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

	Sulfasalazine	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	13995479	EXPEDITED (15-DAY)		OT	CA-ROCHE-1995131		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C				Not Reported
	Estradiol			C				Not Reported
	Furosemide			C				Not Reported
	Valsartan			C				Not Reported
	Xalatan			C	Ophthalmic			Not Reported
	Baclofen			C				Not Reported
	Levaquin			C				Not Reported
	Baclofen			C				Not Reported
	Furosemide			C				Not Reported
	Gravol Ginger			C				Not Reported
	Potassium Chloride			C				Not Reported

	Valsartan	C	Not Reported
	Zingiber Officinale	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	14161744	EXPEDITED (15-DAY)		OT	CA-ROCHE-2014675			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Insomnia	Rituximab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Prefilled Syringe; Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Naprosyn [Naproxen]			S	Oral			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported
	Naprosyn [Naproxen]			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	14166039	EXPEDITED (15-DAY)		OT	CA-SA-2017SA210592			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S	Oral	20 Mg,Qd		Sanofi
	Methotrexate			S	Oral	175 Mg,Qw		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg,Bid		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi
	Enbrel			S	Unknown	50 Mg,Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg,Qow		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	14739695	EXPEDITED (15-DAY)		OT	CA-ROCHE-2104045		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Laboratory Test Abnormal; Red Blood Cell Sedimentation Rate Abnormal	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported

Xeljanz	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	14746352	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009049			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Cyclosporine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	125 Mg, Q.Wk.		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tofacitinib			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Tylenol Arthritis Pain			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	15343031	EXPEDITED (15-DAY)		OT	CA-ROCHE-2178204		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Constipation; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Insomnia; Iodine Allergy; Off Label Use; Pain; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis	Rituximab	S	Intravenous drip	Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Venlafaxine Hydrochloride	S	Unknown		Not Reported
	Venlafaxine Hydrochloride	S	Oral		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Hydrodiuril	C	Unknown		Not Reported
	M-Eslon	C	Unknown		Not Reported
	Morphine	C	Unknown		Not Reported
	Morphine Sulfate	C	Unknown		Not Reported
	Venlafaxine Hydrochloride	C	Oral		Not Reported
	Statex [Morphine Sulfate]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	15415874	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187974			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

Orencia	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Folic Acid	C	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported
Orencia	C	Unknown	Not Reported
Tofacitinib Citrate	C	Unknown	Not Reported
Prednisone	C		Not Reported
Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	15562825	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015053449		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Enbrel			S		Unk		Unknown
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	22.5 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Qd		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	22.5 Mg, Qwk		Pfizer
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S		10 Mg, Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine	S	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	15875870	EXPEDITED (15-DAY)		OT	PHHY2019DE016444		60 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma; Restlessness	Methotrexate			S	Unknown	20 Mg, Qw		Novartis
	Methotrexate			S	Unknown	17.5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	15 Mg, Unk		Novartis
	Benepali			S	Unknown	50 Mg, Qw		Not Reported
	Benepali			S	Unknown	50 Mg		Not Reported
	Hcq			S	Unknown	200 Mg, Unk		Not Reported
	Hcq			S	Unknown	300 Mg, Qd		Not Reported
	Tocilizumab			S	Unknown	162 Mg		Not Reported
	Chloroquine			C	Unknown	300 Mg, Qd		Not Reported
	Hydroxychloroquine			C	Unknown	200 Mg		Not Reported
	Orencia			C	Unknown	125 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	15949612	EXPEDITED (15-DAY)		HO, OT	US-VALIDUS PHARMACEUTICALS LLC-US-2019VAL000034			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Coronary Artery Occlusion; Herpes Zoster; Mobility Decreased; Osteoporosis; Spinal Fracture	Furosemide			S	Unknown	Unk		Validus
	Nifedipine			S	Unknown	Unk		Validus
	Clopidogrel Bisulfate			S	Unknown	Unk		Not Reported
	Famotidine			S	Unknown	Unk		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported
	Doxycycline			S	Unknown	Unk		Not Reported

Trandolapril	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Hydroxychloroquine /00072603/	S	Unknown	Unk	Not Reported
Loperamide	S	Unknown	Unk	Not Reported
Ambien	S	Unknown	Unk	Not Reported
Gabapentin	S	Unknown	Unk	Not Reported
Esomeprazole Magnesium	S	Unknown	Unk	Not Reported
Rosuvastatin Calcium	S	Unknown	Unk	Not Reported
Potassium	S	Unknown	Unk	Not Reported
Glyceryl Trinitrate	S	Unknown	Unk	Not Reported
Metoclopramide Hydrochloride	S	Unknown	Unk	Not Reported
Trazodone Hydrochloride	S	Unknown	Unk	Not Reported
Isosorbide Mononitrate	S	Unknown	Unk	Not Reported
Victoza	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Qod	Not Reported
Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
Humira	S			Not Reported
Flomax /00889901/	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16043043	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057806			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Leflunomide			S		20 Mg, Unk		Sanofi
	Hydroxychloroquine			S		400 Mg, Unk		Sanofi
	Methotrexate			S		20 Mg, Qd		Not Reported
	Actemra			S		8 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Enbrel			S		Unk Unk, Unk		Not Reported
	Orencia			S		750 Mg, Unk		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	C		Unk Unk, Unk	Not Reported
	Meloxicam	C	Unknown	Unk Unk, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16046577	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057860			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S		20 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi
	Methotrexate			S	Oral	175 Mg, Qw		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16046593	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057717			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspepsia; Joint Swelling; Therapy Partial Responder	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Leflunomide			S	Unknown	20 Mg		Sanofi
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	Unk, Unk		Not Reported
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16046595	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057730		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Lower Respiratory Tract Infection; Nasal Congestion; Rhinorrhoea; Synovitis	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Sanofi
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Cimzia			S	Unknown	Unk Unk, Unk		Not Reported
	Salazopyrin			C	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16046597	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057910			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown	20 Mg		Sanofi
	Plaquenil			S	Unknown	200 Mg, Bid		Sanofi
	Methotrexate			S	Unknown	20 Mg		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	(4-6 Months Duration)		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16047223	EXPEDITED (15-DAY)		OT	CA-SA-2019SA058618		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Joint Swelling; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Arava	S	Unknown	20 Mg, Qd		Sanofi
	Plaquenil	S	Unknown	200 Mg, Qow		Sanofi
	Methotrexate	S	Intravenous (not otherwise specified)	20 Mg, Qw		Not Reported
	Actemra	S	Unknown	5 Unk		Not Reported
	Humira	S	Subcutaneous	40 Mg, Qw		Not Reported
	Methotrexate Sodium	S	Unknown	25 Mg, Qw		Not Reported
	Methotrexate Sodium	S		20 Mg, Qw		Not Reported
	Remicade	S	Unknown			Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16048334	EXPEDITED (15-DAY)		OT	CA-SA-2019SA059173			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S	Oral	20 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi
	Methotrexate			S	Oral	175 Mg, Qw		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16051263	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057562			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of	Arava			S	Oral	20 Mg, Unk		Sanofi
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Sanofi
	Sulfasalazine			S	Unknown	1000 G, Unk		Not Reported

Personal Independence In Daily Activities; Pain; Peripheral Swelling	Prednisone		S	Oral	5 Mg, Unk	Not Reported
	Methotrexate		S	Unknown	20 Mg, Unk	Not Reported
	Actemra		S	Unknown	Unk	Not Reported
	Enbrel		S	Unknown	50 Mg, Unk	Not Reported
	Humira		S	Unknown	20 Mg, Unk	Not Reported
	Orencia		S	Unknown		Not Reported
	Xeljanz		C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16075449	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-012871		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Alendronic Acid Tablets			S	Unknown	70 Milligram, Once A Day		Aurobindo
	Alendronic Acid Tablets			S	Unknown	70 Milligram, Once A Day		Aurobindo
	Alendronic Acid Tablets			S	Oral	70 Milligram, Every Week		Aurobindo
	Actemra			S	Unknown	360 Milligram		Not Reported
	Actemra			S	Unknown	680 Milligram, Every Month		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every 1 Week		Not Reported
	Enbrel			S	Unknown	50 Milligram, Every Week		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Everey 2 Week		Not Reported
	Humira			S	Subcutaneous	40 Milligram,11 Every 2 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported

Leflunomide	S	Oral	Unk	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, Every Week	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, Every Week	Not Reported
Methotrexate	S	Unknown	10 Milligram, Every Week	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
Methotrexate	S	Unknown	12 Milligram, Every Week	Not Reported
Methotrexate	S	Unknown	15 Milligram, Every Week	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
Methotrexate	S	Unknown	10 Milligram, Every Week	Not Reported
Methotrexate	S	Oral	10 Milligram, Every Week	Not Reported
Myochrysine	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	780 Milligram, Every Week	Not Reported
Orencia	S	Unknown	780 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	1000 Milligram, Two Times A Day	Not Reported
Myochrysine	S	Intramuscular	50 Milligram	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Two Times A Day	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Tocilizumab	S	Unknown	360 Milligram, Every Month	Not Reported
Alendronate Sodium	C	Unknown	70 Milligram, Every Week	Not Reported
Ciclosporin	C	Unknown	150 Milligram, Once A Day	Not Reported
Prednisone	C	Unknown	10 Milligram, Once A Day	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16462890	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1910		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fall; Gastrointestinal Disorder; Interstitial Lung Disease; Liver Function Test Increased; Sepsis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Pamidronate Disodium			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Cyclosporin			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Stelara			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	6-Mercaptopurine Monohydrate			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Tenoxicam			S	Unknown			Not Reported
	Bromocriptine			S	Unknown			Not Reported
	Ustekinumab			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported

Mercaptopurine	C	Unknown	Not Reported
Methylprednisolone	C	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Dilaudid	C	Unknown	Not Reported
Tenoxicam	C	Unknown	Not Reported
Ustekinumab	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16537906	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA177580		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Hernia; Joint Destruction; Nausea; Rheumatoid Arthritis; Stoma Complication	Hydroxychloroquine			S	Oral	400 Mg, Bid		Sanofi
	Methotrexate			S	Subcutaneous	0.8 Ml, Qw		Not Reported
	Leflunomide			S	Unknown	Unk, Unk		Sanofi
	Prednisone			S	Unknown	Unk, Unk		Not Reported
	Celecoxib			S	Oral	200 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported
	Actemra			S	Unknown	Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16753500	EXPEDITED (15-DAY)		OT	CA-ROCHE-2384248		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Vaccine; Condition Aggravated; Diarrhoea; Drug Ineffective; Fall; Hypersensitivity; Laryngeal Disorder; Larynx Irritation; Nausea; Product Use Issue;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Zostavax		S	Subcutaneous	Therapy Duration-1.0 Day(S)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16811263	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20190905771			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Hospitalisation; Infection; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Paracetamol			S	Unknown			Johnson And Johnson
	Paracetamol			S	Unknown			Johnson And Johnson
	Tylenol Arthritis Pain 8h			S	Unknown			Johnson And Johnson
	Paracetamol/Diphenhydramine Hcl			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 823.0		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Hydroxychloroquine /00072603/		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Oral	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Paracetamol/Codeine Phosphate	C	Unknown	Not Reported
Oros Hydromorphone Hcl	C	Unknown	Not Reported
Tylenol W/ Codeine No. 3	C	Unknown	Not Reported
Celebrex	C	Oral	Not Reported
Celecoxib	C	Unknown	Not Reported
Meloxicam	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Codeine	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16825327	EXPEDITED (15-DAY)		OT	CA-ROCHE-2404671			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Rituximab	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16878285	EXPEDITED (15-DAY)		OT	CA-ROCHE-2107873		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Naproxen			C	Unknown			Not Reported
	Atorvastatin Calcium			C				Not Reported
	Bisoprolol			C				Not Reported
	Digoxin			C				Not Reported
	Folic Acid			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Naproxen			C				Not Reported
	Nifedipine			C				Not Reported
	Synthroid			C				Not Reported
	Toloxin [Digoxin]			C				Not Reported

	Valsartan	C	Not Reported
	Xarelto	C	Not Reported
	Zinc Citrate	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	16913173	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2428710		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Rituxan			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Endocervical	Not Reported
Apremilast	S	Unknown	Not Reported
Apo-Ibuprofen	S	Oral	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Infliximab	S	Oral	Not Reported
Ibuprofen	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Motrin [Ibuprofen]	S	Oral	Not Reported
Otezla	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Stelara	S	Subcutaneous	Not Reported
Alendronate	C	Unknown	Not Reported
Ciclosporin	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Xeljanz	C		Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C		Not Reported

Colchicine	C	Oral		Not Reported
Dexilant	C	Unknown		Not Reported
Febuxostat	C			Not Reported
Folic Acid	C			Not Reported
Gravol	C			Not Reported
Mogadon	C	Oral		Not Reported
Nitrazepam	C	Oral		Not Reported
Oxycodone	C			Not Reported
Uloric	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17233158	EXPEDITED (15-DAY)		HO	CA-ROCHE-2511749			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)		
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Desoximetasone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17286449	EXPEDITED (15-DAY)		OT	CA-ROCHE-2521764			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17324328	EXPEDITED (15-DAY)		OT	MQ-ALKEM LABORATORIES LIMITED-MQ-ALKEM-2020-00067		53 YR	Female	MTQ

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acarodermatitis; Hyperkeratosis	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Azathioprine			S	Unknown	Unk		Alkem
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17417741	EXPEDITED (15-DAY)		HO	CA-ROCHE-2547886		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Hip Arthroplasty; Infection; Knee Arthroplasty; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Naprosyn [Naproxen]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17438985	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552195			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Iron Decreased; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17477176	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2557988			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Joint Arthroplasty; Rheumatoid Arthritis; Weight Increased; Wheelchair User	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Indometacin			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Morphine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported

	Arava	S	Unknown	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17506284	EXPEDITED (15-DAY)		OT	CA-ROCHE-2560155		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported

Minocycline Hydrochloride	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Amoxicillin;Clavulanate Potassium	C		Not Reported
Amoxil [Amoxicillin]	C	Unknown	Not Reported
Adalimumab	C		Not Reported
Amoxicillin	C		Not Reported
Amoxicillin Trihydrate	C		Not Reported
Amoxicillin Trihydrate;Clavulanate Potassium	C		Not Reported
Bcg Vaccine	C	Unknown	Not Reported
Bcg Vaccine	C	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine	C	Unknown	Not Reported
Hydroxychloroquine	C	Subcutaneous	Not Reported
Hydroxychloroquine	C	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported
Risedronate	C	Oral	Not Reported
Gold	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17531084	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2563674		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Joint Range	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

Of Motion Decreased; Memory Impairment; Mobility Decreased; Musculoskeletal Disorder; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17705423	EXPEDITED (15-DAY)		DE, LT, OT	FR-ADVANZ PHARMA-202004003544			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Multiple Organ Dysfunction Syndrome; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg, Qd Film-Coated Tablet		Concordia
	Hydroxychloroquine			S				Concordia
	Metoclopramide Hydrochloride			C		Unk		Not Reported
	Ciprofloxacine			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Piperacilline/Tazobactam			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Lidocaine			C		Unk		Not Reported
	Enoxaparin Sodium			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17716028	EXPEDITED (15-DAY)		DE, OT	FR-ADVANZ PHARMA-202004004070			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Respiratory Distress Syndrome; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Off Label Use; Renal Failure; Respiratory Failure	Hydroxychloroquine	S	Oral	400 Mg, Qd	Concordia
	Ceftriaxone	C		Unk	Not Reported
	Methylprednisolone	C		Unk	Not Reported
	Oxazepam	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17718033	EXPEDITED (15-DAY)		HO, LT, OT	IT-ACCORD-179592		36 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Blood Creatinine Increased; Coronavirus Infection; Diarrhoea; Drug Interaction; Drug Level Above Therapeutic; Glomerular Filtration Rate Abnormal; Nausea; Pneumonia; Vomiting	Tacrolimus			S		Bid, 3 Mg Bid		Accord
	Ceftriaxone			S				Not Reported
	Lopinavir/Ritonavir			S		400mg/100mg Bid		Not Reported
	Hydroxychloroquine			S		Bid		Not Reported
	Methylprednisolone			S		6.5 Mg Daily		Not Reported
	Allopurinol			C				Not Reported
	Atorvastatin			C				Not Reported
	Ramipril			C				Not Reported
	Omeprazole			C				Not Reported
	Tacrolimus			S		Bid, 3 Mg Bid		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17719494	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1227982		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Cardiotoxicity	Hydroxychloroquine			S	Unknown			Teva
	Rituximab			C	Unknown			Not Reported
	Cyclophosphamide			C	Unknown			Not Reported
	Doxorubicin Hydrochloride			C	Unknown			Not Reported
	Vincristine			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17720141	EXPEDITED (15-DAY)		DE, OT	ES-PFIZER INC-2020167361		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Off Label Use; Product Use In Unapproved Indication; Product Use Issue; Sudden Death	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 1x/Day		Not Reported
	Levofloxacin			S		Unk		Not Reported
	Lopinavir + Ritonavir			S	Oral	2 Df, 2x/Day		Not Reported
	Tacrolimus			S	Oral	Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Enoxaparin Sodium			C	Subcutaneous	40 Mg, 1x/Day		Not Reported
	Prednisone			C	Oral	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17726348	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202004004068			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pneumonia; Renal Failure	Hydroxychloroquine			S		400 Mg, Qd (Film-Coated Tablet)		Concordia
	Hydroxychloroquine			S				Concordia
	Cefepime			S	Intravenous (not otherwise specified)	6 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17737424	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2020-021232		96 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Extrasystoles; Off Label Use	Azithromycin Film-Coated Tablets			S	Unknown	500 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Unknown	400 Milligram, Once A Day		Not Reported
	Lasix			C	Unknown	25 Milligram, Once A Day		Not Reported

Novorapid	C	Unknown	Unk		Not Reported
Normix	C	Unknown	Unk		Not Reported
Dobetin	C	Unknown	Unk		Not Reported
Lantus	C	Unknown	Unk		Not Reported
Movicol	C	Unknown	Unk		Not Reported
Deltacortene	C	Unknown	Unk		Not Reported
Pantorc	C	Unknown	20 Milligram, Once A Day		Not Reported
Cardirene	C	Unknown	75 Milligram, Once A Day		Not Reported
Metoprololo	C	Unknown	50 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17747047	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3389331-00		70 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Off Label Use; Vomiting	Kaletra			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17753394	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-021569		78 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Long Qt Syndrome	Azithromycin			S	Unknown	Unk,Not Specified		Aurobindo
	Ceftriaxone			S	Unknown	Unk,Not Specified		Not Reported
	Midazolam			S	Unknown	Unk		Not Reported
	Midazolam			S				Not Reported
	Propofol			S	Unknown	Unk		Not Reported
	Propofol			S				Not Reported
	Dolquine			S	Oral	200 Milligram, Two Times A Day (A Compressed Breakfast And Dinne)		Not Reported
	Kaletra			S	Oral	Unk		Not Reported

Manidon Hta	C	Unknown	Unk		Not Reported
Rilast	C	Unknown	Unk		Not Reported
Omnic Ocas	C	Unknown	Unk		Not Reported
Simvastatin	C	Unknown	Unk		Not Reported
Kalpress	C	Unknown	Unk		Not Reported
Cortic	C	Unknown	Unk,Low Dose Corticoids		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17763611	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1045811		54 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg/24h		Not Reported
	Azithromycin			S				Not Reported
	Hydroxychloroquine			S	Oral	200 Mg/12h		Not Reported
	Hydroxychloroquine			S				Not Reported
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	2gr/24h		Mylan
	Ceftriaxona /00672201/			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17768365	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597019			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Joint Swelling; Musculoskeletal Stiffness; Presyncope	Rituximab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Folic Acid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17768422	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596002			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported
	Varilrix			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			C	Oral			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17768752	EXPEDITED (15-DAY)		HO	CA-ROCHE-2593341			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Hospitalisation; Infection; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Actemra	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Acetaminophen	S	Unknown		Not Reported
	Acetaminophen	S	Unknown		Not Reported
	Diphenhydramine Hydrochloride;Paracetamol;Phenylephrine Hydrochloride	S	Unknown		Not Reported
	Apo-Acetaminophen	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Doxycycline	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	Therapy Duration: 823.0	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Oral	Therapy Duration: 4.0 Months	Not Reported
	Orencia	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Tylenol	S	Unknown		Not Reported
	Synthroid	C			Not Reported
	Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17768780	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595810		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Gait Inability; Hypoaesthesia; Pharyngeal Oedema; Rash	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17768816	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-023990		48 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Paracetamol			S	Oral	1 Gram, 3 Times A Day		Aurobindo
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S				Not Reported
	Cefditoren Pivoxil			S	Oral	400 Milligram, Two Times A Day		Not Reported
	Cefditoren Pivoxil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17768910	EXPEDITED (15-DAY)		LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-246775		56 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Olanzapine			S	Oral	7.5 Milligram, Daily		Sun
	Plaquenil 200 Mg, Comprime Pellicule			S	Oral	800 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17769128	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595786		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Presyncope; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate Sodium			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17769203	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596166			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Orencia		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Methotrexate		S	Other		Not Reported
	Methotrexate		S	Oral		Not Reported
	Humira		S	Unknown		Not Reported
	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Gold		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Celebrex		C	Unknown		Not Reported
	Leflunomide		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17769259	EXPEDITED (15-DAY)		DE	ES-ABBVIE-20K-144-3399543-00		82 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Kaletra 200/50			S	Oral			Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)			Not Reported
	Azitromicina			S	Intravenous (not otherwise specified)			Not Reported
	Dolquine			S	Oral			Not Reported
	Enalapril + Hidroclorotiazida			C	Oral			Not Reported
	Omeprazol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17769297	EXPEDITED (15-DAY)		HO	FR-CADILA HEALTHCARE LIMITED-FR-ZYDUS-050486			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Loss Of Consciousness; Malaise; Ventricular Extrasystoles	Azithromycin			S	Oral	Unk		Zydus Pharm
	Plaquenil Sulfate			S	Oral	Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			C	Oral	Unk		Not Reported
	Paracetamol			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17769446	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596822			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17769515	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596608		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Hepatic Enzyme Abnormal; Pneumonia; Rheumatoid	Rituxan			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Arthritis; Vomiting	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Salazopyrin	S	Unknown	Not Reported
	Loperamide	C		Not Reported
	Pantoprazole	C		Not Reported
	Xeljanz	C		Not Reported
	Align	C		Not Reported
	Actemra	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17769595	EXPEDITED (15-DAY)		HO	CA-ROCHE-2596962			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Confusional State; Drug Ineffective; Fall; Headache; Injury; Muscular Weakness; Nausea; Off Label Use; Treatment Failure; Vomiting	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17769616	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202004005067			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Diarrhoea; Drug	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia

Ineffective; Drug Intolerance; Joint Swelling; Psoriatic Arthropathy; Treatment Failure	Methotrexate		S	Unknown	Unk	Not Reported
	Leflunomide		S	Unknown	20 Mg, Qd	Not Reported
	Sulfasalazine		S	Oral	2 G, Qd	Not Reported
	Fish Oil		S	Oral	Unk, Qd	Not Reported
	Inflectra		S	Unknown	5 Mg/Kg Q 0, 2, 6 Weeks	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17769657	EXPEDITED (15-DAY)		DE, OT	FR-ADVANZ PHARMA-202004004987			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Death; General Physical Health Deterioration; Off Label Use; Tachypnoea	Hydroxychloroquine			S	Oral	400 Mg, Qd, Film Coated Tablet		Concordia
	Alfuzosine [Alfuzosin]			C		Unk		Not Reported
	Acetylsalicylic Acid			C		Unk		Not Reported
	Macrogol			C		Unk		Not Reported
	Nebivolol			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Calciparine			C		Unk		Not Reported
	Fresubin [Caffelne;Carbohydrates Nos;Fats Nos;Flbre, Dletary;Mlnerals			C		Unk		Not Reported
	Prednisolone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17769658	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202004004919			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	600 Mg, Qd		Concordia
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Concordia

(Authorized Generic),Plaquenil

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770015	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596364			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy; Synovitis	Rituximab			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770068	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004005236			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myopia; Retinopathy; Systemic Lupus Erythematosus; Visual Acuity Reduced	Hydroxychloroquine			S		600 Mg, Qd		Concordia
	Hydroxychloroquine			S		400 Mg, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770137	EXPEDITED (15-DAY)		HO	CA-ROCHE-2595745			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug	Rituxan			S	Intravenous drip			Not Reported

Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Methotrexate	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770159	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US-001362			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Astigmatism; Cornea Verticillata; Corneal Toxicity; Eyelid Ptosis; Punctate Keratitis	Hydroxychloroquine			S	Unknown	600 Milligram, Bid		Ipca
	Hydroxychloroquine			S	Unknown	1200 Milligram, Qd		Ipca
	Everolimus			C	Unknown	10 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770289	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235380		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Swelling; Joint Swelling; Nasopharyngitis; Rheumatoid Arthritis; Suicidal Ideation	Alendronate Sodium		C	Unknown	Not Reported
	Fosamax		C	Unknown	Not Reported
	Ibuprofen		C	Unknown	Not Reported
	Lisinopril		C	Unknown	Not Reported
	Vitamin D3		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770291	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234164			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mood Altered; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770292	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1234235			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Dehydration; Drug Ineffective	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770293	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235381		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Pain; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770303	EXPEDITED (15-DAY)		HO	CA-ROCHE-2596964		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Infusion Related Reaction; Off Label Use; Pharyngeal Swelling; Poor Venous Access; Vasculitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Epinephrine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Fentanyl			C				Not Reported
	Losartan			C				Not Reported
	Mirtazapine			C				Not Reported
	Progesterone			C				Not Reported
	Rabeprazole			C				Not Reported
	Sertraline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770331	EXPEDITED (15-DAY)		HO, LT, OT	JP-ACCORD-181070		41 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Disorder; Exposure During Pregnancy; Hormone Level Abnormal; Hypogonadism; Infarction; Pelvic Infection; Placenta Accreta; Pre-Eclampsia; Proteinuria; Vaginal Haemorrhage	Tacrolimus			S				Accord
	Estradiol			S	Transdermal			Not Reported
	Progesterone			S	Vaginal			Not Reported
	Dydrogesterone			S	Oral			Not Reported
	Prednisolone			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770353	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235370		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Musculoskeletal Stiffness; Pain; Pulmonary Fibrosis	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770367	DIRECT	Y	HO, OT			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tachyarrhythmia	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin 500mg Daily			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770369	EXPEDITED (15-DAY)		HO	CA-ROCHE-2597007			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Injury; Nausea; Product Label Confusion; Treatment Failure; Vomiting	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cimzia			C	Subcutaneous			Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770516	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596382		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Presyncope; Treatment Failure	Rituximab			S	Unknown	Therapy Duration: 7.0 Years		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

Methotrexate	S	Subcutaneous		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Prednisone	C	Oral		Not Reported
Xeljanz	C	Oral		Not Reported
Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770677	DIRECT	Y	HO, OT			85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Ventricular Extrasystoles	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770905	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2020185534		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Product Use Issue	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported
	Rocephine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770950	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057628		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Leukopenia; Nausea; Treatment Failure; Vomiting; Weight	Arava			S	Unknown	20 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	300.0 Mg, Unk		Sanofi

Decreased	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Bid		Sanofi
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg		Sanofi
	Methotrexate	S	Unknown	15.0 Mg, Qw		Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17771123	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1045657		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Sotalol			S	Oral	80 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	600 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17771147	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595696		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Body Height Decreased; Contraindicated Product Administered; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Rheumatoid Arthritis	Rituxan			S	Intravenous drip			Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Orencia			S	Unknown	3.0 Months		Not Reported
	Methotrexate			S	Unknown	366.0		Not Reported
	Arava			S	Unknown	366.0		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	366.0		Not Reported
	Lyrica			S	Unknown	366.0		Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Lumigan Rc			C	Ophthalmic			Not Reported
	Esomeprazole			C	Unknown			Not Reported

Sulfasalazine	C	Unknown	Not Reported
Trazodone	C	Unknown	Not Reported
Tylenol	C	Unknown	Not Reported
Tylenol Extra Strength	C	Unknown	Not Reported
Valsartan	C	Unknown	Not Reported
Wellbutrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17771350	EXPEDITED (15-DAY)		DE, OT	MX-ADVANZ PHARMA-202004004924			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Bilirubin Conjugated Abnormal; Blood Creatinine Increased; Death; Off Label Use	Hydroxychloroquine			S		200 Mg, Bid		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17771351	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004004723			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Macular Degeneration; Toxicity To Various Agents	Hydroxychloroquine			S		Unk, Duration For Less Than 3 And Half Yeas		Concordia
	Prednisone			S		Unk,10 To 20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17771443	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1045786		73 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Haemorrhage; Hepatitis	Piperacillin/Tazobactam			S	Intravenous (not otherwise specified)	C/24 H		Not Reported

Acute	Azithromycin	S	Oral	500 Mg Dia		Not Reported
	Ertapenem	S	Intravenous (not otherwise specified)	1 G Dia		Mylan
	Dolquine	S	Oral	400 Mg Dia		Mylan
	Dolquine	S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17771446	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1045819		52 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis Cholestatic	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Azithromycin			S				Not Reported
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	2 G Dia		Mylan
	Ceftriaxona /00672201/			S				Mylan
	Dolquine			S	Oral	400 Mg Dia		Mylan
	Dolquine			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17771597	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590775		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Therapeutic Product Effect	Actemra			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Unknown			Not Reported

Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Visual Impairment	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Depo-Medrol	C	Intra-articular	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Prednisone	C	Unknown	Not Reported
	Sulfasalazine	C	Oral	Not Reported
	Tylenol	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17771612	EXPEDITED (15-DAY)		HO, LT	ES-PFIZER INC-2020187944		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia; Off Label Use; Pancreatitis Acute; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Methylprednisolone Sodium Succinate			S	Intravenous (not otherwise specified)	250 Mg, 1x/Day		Pfizer
	Kaletra			S	Oral	2 Df, 2x/Day (Every 12 Hours)		Not Reported
	Ceftriaxon			S	Intravenous (not otherwise specified)	1 G, 1x/Day		Not Reported
	Dolquine			S	Oral	200 Mg, 2x/Day (Every 12 Hours)		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	560 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17771649	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2591841		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe (Subcutaneous Solution)		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution (Intravenous)		Not Reported
	Simponi			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17771827	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2020185943		76 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Erythema; Rash Pustular	Norvasc			S	Oral	10 Mg, 1x/Day		Pfizer
	Norvasc			S		Unk (Reduced Dose)		Pfizer
	Ritonavir			S	Oral	100 Mg, 1x/Day		Not Reported

Clexane T	S	Subcutaneous	6000 Kiu, 1x/Day	Not Reported
Darunavir	S	Oral	800 Mg, 1x/Day	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Mg, 1x/Day	Not Reported
Azithromycin Teva	S	Oral	500 Mg, 1x/Day	Not Reported
Eutirox	C		Unk	Not Reported
Folifill	C		Unk	Not Reported
Ceftriaxone	C	Oral	1 Df, 1x/Day	Not Reported
Lasix [Furosemide]	C		Unk	Not Reported
Urbason Solub	C	Intravenous (not otherwise specified)	1 Df, 1x/Day	Not Reported
Omeprazole	C		Unk	Not Reported
Trelegy Ellipta	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17772487	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20200512027			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Darunavir			S	Unknown			Janssen
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17773499	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3399921-00		67 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Rash Pruritic	Kaletra 200/50			S	Oral			Not Reported
	Levofloxacino			S	Intravenous (not otherwise specified)			Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported
	Azitromicina			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17773527	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-024316		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Hypofibrinogenaemia; Upper Gastrointestinal Haemorrhage	Meropenem			S	Intravenous (not otherwise specified)	1 Gram, 3 Times A Day		Aurobindo
	Piperacillin+Tazobactam 4.5g			S	Intravenous (not otherwise specified)	1 Dosage Form, 3 Times A Day		Aurobindo
	Linezolid			S	Intravenous (not otherwise specified)	600 Milligram, Two Times A Day		Aurobindo
	Roactemra			S	Unknown	600 Milligram,1 Total		Not Reported
	Roactemra			S				Not Reported
	Metamizole			S	Intravenous (not otherwise specified)	2 Gram, 3 Times A Day		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17773531	EXPEDITED (15-DAY)		HO	ES-AUROBINDO-AUR-APL-2020-024317		83 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hyponatraemia	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported
	Hydroxychloroquine Phosphate			S	Oral	400 Milligram, Once A Day		Not Reported
	Salbutamol			S	Respiratory (inhalation)	2-2-2 Inh		Not Reported
	Symbicort Turbuhaler			S	Respiratory (inhalation)	2 Dosage Form, 3 Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	11176748	EXPEDITED (15-DAY)		OT	CA-ROCHE-1589866		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspepsia; Liver Function Test Abnormal; Liver Function Test Increased; Liver Function Test Increased; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Response Decreased	Rituxan			S	Intravenous (not otherwise specified)	Discontinued After 2 Cycles, Therapy Duration: 4 Months.		Not Reported
	Humira			S	Subcutaneous	For 4 Years		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 8 Years		Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral	Therapy Duration: 4 Months		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 6 Months		Not Reported
	Tofacitinib			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	12678680	EXPEDITED (15-DAY)		OT	CA-ROCHE-1817079		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Laboratory Test Abnormal; Red Blood Cell Sedimentation Rate Abnormal	Rituxan			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

	Methotrexate Sodium			S	Unknown				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Orencia			S	Unknown				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	12884262	EXPEDITED (15-DAY)		OT	CA-ROCHE-1734356		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Nasopharyngitis; Neutropenia; Platelet Count Decreased; Respiratory Tract Infection Viral; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Actemra			S	Unknown	Discontinued		Not Reported
	Enbrel			S	Unknown	Discontinued		Not Reported
	Orencia			S	Unknown	Discontinued		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown	Therapy Duration: 4 Months		Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Leflunomide	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Folic Acid	C		Not Reported
	Naproxen	C		Not Reported
	Advil [Ibuprofen]	C		Not Reported
	Ketorolac	C		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported
	Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	12988986	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-ROCHE-1860198			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Marijuana			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Sulfasalazine	S	Oral	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Arava	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Ilaris	S	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	13203126	EXPEDITED (15-DAY)		OT	CA-ROCHE-1889218		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Leflunomide	S	Unknown		Not Reported
Humira	S	Subcutaneous	Cyclical	Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Unknown		Not Reported
Humira	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Remicade	S	Unknown		Not Reported
Remicade	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Anakinra	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Xeljanz	C	Unknown		Not Reported
Sulfasalazine	C	Unknown		Not Reported

	Wellbutrin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	13281112	EXPEDITED (15-DAY)		OT	CA-ROCHE-1898409		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug Resistance; Fatigue; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rheumatoid Arthritis; Rotator Cuff Syndrome; Swelling; Therapeutic Response Decreased; Tongue Ulceration; Tooth Infection; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Abatacept			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Nystatin			S	Unknown			Not Reported
	Nystatin			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported
	Indocine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	13842763	EXPEDITED (15-DAY)		OT	CA-ROCHE-1973086			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Adverse Event; Alopecia; Bronchitis Chronic; Contraindicated	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; General Symptom; Neck Pain; Neck Surgery; Off Label Use; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis; Treatment Failure	Actemra	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Rituxan	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Mobicox	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	15364714	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2181752		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Blood Creatine Decreased; Condition Aggravated; Drug Ineffective; Drug	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not			Not Reported

Intolerance; Eye Discharge; Eye Disorder; Eye Operation; Eye Pain; Fatigue; Glaucoma; Haematocrit Decreased; Haemoglobin Decreased; Headache; Inflammation; Lacrimation Increased; Lymphocyte Count Increased; Monocyte Count Increased; Nasopharyngitis; Nausea; Neutrophil Count Decreased; Ocular Procedural Complication; Optic Neuritis; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Tinnitus; Vision Blurred; White Blood Cell Count Decreased			otherwise specified)	
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Acetaminophen	S	Unknown	Not Reported
	Apo Hydromorphone	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Dilaudid	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Acetaminophen	S	Oral	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Alendronate Sodium;Colecalciferol	C	Unknown	Not Reported
	Alendronate Sodium;Colecalciferol	C	Unknown	Not Reported

	Humira	C	Unknown	Not Reported
	Hydrocortisone	C	Nasal	Not Reported
	Hyzaar	C	Unknown	Not Reported
	Hyzaar	C	Unknown	Not Reported
	Methylprednisolone	C		Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Not Reported
	Remicade	C	Unknown	Not Reported
	Diphenhydramine Hydrochloride	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	15843027	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20190118848		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Foot Deformity; Foot Operation; Infection; Limb Discomfort; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Risedronate Sodium	S	Unknown	Not Reported
	Risedronate Sodium	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Actonel	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Risedronic Acid	S	Unknown	Not Reported
	Hydroxychloroquine	C	Oral	Not Reported
	Hydroxychloroquine	C		Not Reported
	Risedronate	C	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	16046574	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA057903		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Exostosis; Osteoarthritis; Pain In Extremity; Pulmonary Thrombosis; Thrombosis	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Bid		Sanofi
	Pantoprazole			C	Unknown	40 Mg, Qd		Not Reported
	Pravastatin			C	Unknown	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	16055947	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA057819		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure; Unevaluable Event; Unevaluable Event	Arava			S	Oral	20 Mg, Qd		Sanofi
	Gabapentin			S	Unknown	Unk		Not Reported
	Gabapentin			S	Unknown	100 Mg, Unk		Not Reported
	Celecoxib			S	Oral	Unk		Not Reported
	Celecoxib			S	Oral	Unk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Oxycodone			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Sanofi
	Sulfasalazine			S	Oral	2.5 G, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Sanofi
	Methotrexate			S	Subcutaneous	Unk Unk, Qw		Not Reported
	Myochrysine			S	Intramuscular	50 Mg, Q3w		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488 Mg, Qm		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Qm		Not Reported
	Omega 3 [Fish Oil]			C	Oral	1200 Mg, Bid		Not Reported
	Omega 3 [Fish Oil]			C	Unknown	Unk		Not Reported
	Aclasta			C	Intravenous (not otherwise specified)	750 Mg, Unk		Not Reported
	Actonel			C	Unknown	36 Mg, Qw		Not Reported
	Ascorbic Acid			C	Unknown	Unk		Not Reported
	Biotin			C	Unknown	Unk		Not Reported
	Calcium			C	Unknown	Unk		Not Reported

D-Alpha Tocopherol	C	Unknown	1200 Mg, Bid	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	Unk Unk, Qd	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg	Not Reported
Ergocalciferol	C	Unknown	400 Iu, Qd	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	40 Mg, Bid	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Mg, Bid	Not Reported
Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported
Fish Oil	C	Unknown	1200 Mg, Bid	Not Reported
Genteal [Hypromellose]	C	Unknown	Unk	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Mg, Unk	Not Reported
Nasonex	C	Unknown	Unk	Not Reported
Nexium [Esomeprazole Magnesium]	C	Unknown	Unk	Not Reported
Nicotinamide	C	Unknown	Unk Unk, Bid	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Mg, Qcy	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Unk	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	400 Mg, Qd	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Mg, Qd	Not Reported
Prednisone	C	Unknown	5 Mg, Qd	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Sodium	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Trazodone [Trazodone Hydrochloride]	C	Oral	50 Mg, Qcy	Not Reported
Tylenol [Paracetamol]	C	Unknown	50 Mg, Qcy	Not Reported
Vit D3	C	Unknown	Unk	Not Reported
Vitamin A [Retinol]	C	Unknown	Unk	Not Reported
Vitamin B12 [Vitamin B12 Nos]	C	Unknown	Unk	Not Reported

	Vitamin D [Vitamin D Nos]	C	Unknown	400 Df, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Qd	Not Reported
	Thiamine Hcl	C			Not Reported
	Oxycodone And Acetaminophen	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	16341891	EXPEDITED (15-DAY)		HO, OT	US-VALIDUS PHARMACEUTICALS LLC-US-2019VAL000245			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Coronary Artery Occlusion; Diabetes Mellitus; Herpes Zoster; Mobility Decreased; Osteoporosis; Spinal Fracture	Furosemide			S	Unknown	Unk		Validus
	Nifedipine			S	Unknown	Unk		Validus
	Famotidine			S	Unknown	Unk		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported
	Trandolapril			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Plavix			S	Unknown	Unk		Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	Unk		Not Reported
	Glyceryl Trinitrate			S	Unknown	Unk		Not Reported
	Rosuvastatin Calcium			S	Unknown	Unk		Not Reported
	Metoclopramide Hydrochloride			S	Unknown	Unk		Not Reported
	Trazodone Hydrochloride			S	Unknown	Unk		Not Reported
	Loperamide Hydrochloride			S	Unknown	Unk		Not Reported
	Ambien			S	Unknown	Unk		Not Reported
	Gabapentin			S	Unknown	Unk		Not Reported
	Esomeprazole Magnesium			S	Unknown	Unk		Not Reported
	Flomax /00889901/			S	Unknown	Unk		Not Reported
	Isosorbide Mononitrate			S	Unknown	Unk		Not Reported
	Potassium Acetate			S	Unknown	Unk		Not Reported
	Victoza			S	Unknown	Unk		Not Reported

Humira	S	Subcutaneous	40 Mg, Qow		Not Reported
Humira	S	Subcutaneous	40 Mg, Qow		Not Reported
Doxycycline Hyclate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	16388022	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-029850		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Confusional State; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Osteoarthritis; Pain; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Lisinopril Tablet			S	Unknown	Unk		Aurobindo
	Lisinopril Tablet			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Oral	Unk		Aurobindo
	Diclofenac			S	Oral	75 Milligram, Two Times A Day		Not Reported
	Diclofenac			S	Oral	75 Milligram, As Necessary		Not Reported
	Diclofenac			S	Oral	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Every Week		Not Reported
	Plaquenil			S	Oral	200 Milligram, Once A Day		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	2 Gram, Once A Day		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Two Times A Day		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Once A Day		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Tecta			S	Oral	Unk		Not Reported
	Xeljanz			S	Oral	10 Milligram, Once A Day		Not Reported
	Voltaren			S	Oral	75 Milligram, Two Times A Day		Not Reported
	Voltaren			S	Oral	Unk		Not Reported

Apo-Folic Acid	S	Unknown	Unk	Not Reported
Apo-Diclofenac	S	Oral	75 Milligram, Two Times A Day	Not Reported
Apo-Diclofenac	S	Oral	75 Milligram	Not Reported
Apo-Lisinopril	S	Unknown	Unk	Not Reported
Depo-Medrol	C	Intramuscular	Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	16740198	EXPEDITED (15-DAY)		OT	DE-DRREDDYS-GER/GER/19/0113518			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Oedema Peripheral; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Ramipril			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Not Reported
	Ramipril			S				Not Reported
	Omeprazole			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Not Reported
	Omeprazole			S		20 Mg, Bid		Not Reported
	Sildenafil			S	Unknown	60 Milligram, Daily Dose		Not Reported
	Volibris			S	Oral	30 Milligram, Qd		Not Reported
	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qw		Not Reported
	Roactemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1-0-1)		Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1-0-1)		Not Reported
	Eliquis			S	Unknown	1 Df, Bid (1-0-1)		Not Reported
	Spasmolyt			S		1 Df, Qd (1-0-1)		Not Reported
	Spasmolyt			S	Unknown	30 Mg (0 -0 -1)		Not Reported

Spasmolyt	S	Unknown	15 Mg, Qd		Not Reported
Ambrisentan	S	Unknown			Not Reported
Ambrisentan	S	Unknown	30 Milligram, Qd		Not Reported
Ambrisentan	S	Unknown			Not Reported
Ambrisentan	S				Not Reported
Lyrica	S	Unknown	100 Milligram, Tid		Not Reported
Lyrica	S	Unknown	100 Milligram, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17024666	EXPEDITED (15-DAY)		OT	CA-ROCHE-2459897			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Bifidobacterium Bifidum			C	Unknown			Not Reported
	Loperamide			C	Oral			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17046117	EXPEDITED (15-DAY)		DE, HO, LT	CA-ROCHE-2465588		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ilaris			S	Subcutaneous	Single-Use Vial: Powder For Solution For Injection		Not Reported
	Ilaris			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S				Not Reported

Sulfate]					
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution For Infusion		Not Reported
Remicade	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Arava	S	Oral			Not Reported
Arava	S				Not Reported
Cannabis Sativa	S	Unknown			Not Reported
Minocycline	S	Unknown			Not Reported
Minocycline Hydrochloride	S	Unknown			Not Reported
Sodium Aurothiomalate	S	Parenteral			Not Reported
Sodium Aurothiomalate	S	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported
Rituximab	C	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported
Xeljanz	C	Oral			Not Reported
Anakinra	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17114110	EXPEDITED (15-DAY)		OT	CA-SA-2019SA336230			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Sanofi
	Arava			S	Oral	Unk		Sanofi
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk (Not Specified (1 Mg)		Not Reported
	Alendronate Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Sanofi
	Hydroxychloroquine			S	Unknown	400 Mg, Qd, 1 In 1 D		Sanofi

Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Methotrexate	S	Intra-arterial	25 Mg, Qd	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 G	Not Reported
	Sulfasalazine	S	Unknown	2 Gm (1 Gm,1 In 12 H)	Not Reported
	Cortisone Acetate	S	Unknown	25 Mg	Not Reported
	Cimzia	S	Subcutaneous	Unk (Single-Use Prefilled Syringe)	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Phosphate	S	Unknown	400 Mg, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17407151	EXPEDITED (15-DAY)		OT	CA-ROCHE-1698470		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Impaired Work Ability; Infection; Insomnia;	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip	Solution Intravenous		Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 7.0 Months		Not Reported

Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To A General Medical Condition	Arava	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	5.0 Months	Not Reported
	Gold	S	Unknown	7.0 Months	Not Reported
	Gold	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	3.0 Years	Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17416504	EXPEDITED (15-DAY)		HO	US-ACTELION-A-US2020-201797		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacteraemia; Blood Culture Positive; Brevibacterium Infection; Catheter Management; Catheter Site Infection; Device Related Infection; Diarrhoea; Dyspnoea Exertional; Ear Infection; Immunosuppression; Sepsis	Opsumit			S	Oral	10 Mg, Qd		Actelion
	Veletri			S	Intravenous (not otherwise specified)	28 Ng/Kg, Per Min		Actelion
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Letairis			C				Not Reported
	Xarelto			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17492232	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201703-001950			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine			S	Unknown	Unk, Tablet		Concordia
	Hydroxychloroquine			S	Unknown	Unk, Tablet		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Arava			S	Oral	Unk Unk, Weekly		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	640 Mg, Weekly		Not Reported
	Actemra			S	Unknown	640 Unk		Not Reported
	Actemra			S	Unknown	640 Unk		Not Reported
	Apo-Cyclosporine			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Weekly		Not Reported
	Cimzia			S	Subcutaneous	Unk Single-Use Prefilled Syringe		Not Reported
	Enbrel			S		50 Mg, Weekly		Not Reported
	Enbrel			S	Unknown	50 Unk		Not Reported
	Enbrel			S	Unknown	50 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg, Weekly		Not Reported
	Humira			S	Unknown	40 Unk		Not Reported
	Humira			S	Unknown	40 Mg, Weekly		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Weekly		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Certolizumab			S	Subcutaneous	200 Mg, Weekly		Not Reported
	Certolizumab			S	Unknown	200 Unk		Not Reported

	Certolizumab	S	Unknown	200 Mg	Not Reported
	Pregabalin	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Weekly	Not Reported
	Infliximab	S	Unknown	300 Mg, Weekly	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Ciclosporin	S	Oral	Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Piroxicam	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17558038	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318943		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Hypersensitivity; Joint Swelling; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Off Label Use; Pain; Rheumatic Fever; Rheumatoid Arthritis; Spinal Stenosis; Synovitis; Therapeutic Product Effect Decreased; Treatment	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Failure; Type 2 Diabetes Mellitus; Unevaluable Event; Urinary Tract Infection	Actemra		S	Unknown	Not Reported
	Tofacitinib Citrate		S	Oral	Not Reported
	Topicort /00028604/		S	Unknown	Not Reported
	Xeljanz		S	Oral	Not Reported
	Prednisone		S	Oral	Not Reported
	Plaquenil /00072602/		S	Oral	Not Reported
	Celebrex		C	Unknown	Not Reported
	Gold		C		Not Reported
	Morphine		C	Unknown	Not Reported
	Tofacitinib		C	Oral	Not Reported
	Acetaminophen W/Dextropropoxyphene		C		Not Reported
	Desoximetasone		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17586718	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015347561		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dyspnoea; Lower Respiratory Tract Infection; Pain	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17644416	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202003002706			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Off Label Use; Pulmonary Embolism; Respiratory Failure; Septic	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		400 Mg, Qd (Film-Coated Tablet)		Concordia
	Morphine			C		Unk		Not Reported

Shock

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17655387	EXPEDITED (15-DAY)		OT	IT-ABBVIE-20K-083-3357377-00		76 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Ventricular Tachycardia	Kaletra			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17667419	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200409451		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Confusional State; Contraindicated Product Administered; Contusion; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Infusion Related Reaction; Irritable Bowel Syndrome; Joint Swelling;	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)	Cyclical		Janssen
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Chloraprep			S		Topical		Not Reported
	Chlorhexidine Gluconate			S	Unknown	Oral Rinse		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Pain; Pemphigus; Pericarditis; Peripheral Swelling; Pregnancy; Pruritus; Pyrexia; Rash; Rheumatoid Arthritis; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Weight Increased; Wound	Leflunomide	S	Oral		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Oxycodone	S			Not Reported
	Oxycodone Hydrochloride	S			Not Reported
	Oxycodone Terephthalate	S			Not Reported
	Oxycodone And Acetaminophen	S	Unknown		Not Reported
	Periogard	S	Buccal	Alcohol Free	Not Reported
	Sulfamethoxazole	S			Not Reported
	Sulfamethoxazole And Trimethoprim	S			Not Reported
	Arava	S	Oral		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Cetirizine	S	Unknown		Not Reported
	Cetirizine Hydrochloride W/Pseudoephedrine Hy	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Plaquenil /00072602/	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Cortisone	S	Topical		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Diclofenac	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfathalidine	S	Oral	Not Reported
	Sulfathalidine	S	Oral	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Topicort /00028604/	S	Cutaneous	Not Reported
	Chlorhexidine	S	Unknown	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Cetirizine Hydrochloride	C		Not Reported
	Desogestrel And Ethinylestradiol	C		Not Reported
	Ibuprofen	C		Not Reported
	Pantoloc /01263201/	C		Not Reported
	Pantoprazole Sodium	C		Not Reported
	Paracetamol/Codeine	C		Not Reported
	Reactine /00884302/	C		Not Reported
	Tylenol /00020001/	C		Not Reported
	Tylenol With Codeine	C		Not Reported
	Atasol /00020001/	C	Unknown	Not Reported
	Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17688626	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202004002981			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Diabetic Metabolic Decompensation; Haemoglobin Decreased; Hepatocellular Injury; Infection; Inflammation; Off Label Use; Pyrexia; Respiratory Disorder	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		1200 Mg, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		400 Mg, Qd Film-Coated Tablet		Concordia
	Lovenox			S	Subcutaneous	0.6 Ml, Qd		Not Reported
	Midazolam			S	Intravenous (not otherwise specified)	5 Milligram Per Millilitre, Qd		Not Reported

	Omeprazole	S	Intravenous (not otherwise specified)	20 Mg, Qd	Not Reported
	Omeprazole	S	Intravenous (not otherwise specified)	40 Mg, Qd	Not Reported
	Loxen [Loxoprofen Sodium]	S	Intravenous (not otherwise specified)	30 Mg, Qd	Not Reported
	Movicol	S		2 Dosage Form Bag	Not Reported
	Paracetamol	C		Unk	Not Reported
	Paracetamol	C			Not Reported
	Lasilix	C		Unk	Not Reported
	Novorapid	C		Unk	Not Reported
	Doliprane	C		Unk	Not Reported
	Diffu K	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17726014	EXPEDITED (15-DAY)		OT	NVSC2020CA115075		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain;	Diclofenac			S	Unknown	Unk		Novartis
	Methotrexate			S	Oral	25 Mg		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Folic Acid			S	Oral	25 Mg		Not Reported
	Pseudoephedrine Hcl			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Mg		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg		Not Reported
	Topicort			S	Subcutaneous	Unk		Not Reported

Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Topicort	S	Topical	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	400 Mg	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	4 Mg	Not Reported
	Humira	S	Unknown	400 Mg	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg, Qd	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1 G, Bid	Not Reported
	Sulfasalazine	S	Oral	1 G, Qd	Not Reported
	Sulfathalidine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	5 Mg, Bid	Not Reported
	Xeljanz	S	Unknown	5 Mg, Qd	Not Reported
	Xeljanz	S	Unknown	5 Mg, Bid	Not Reported
	Xeljanz	S	Unknown	5 Mg, Bid	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported

Apo-Prednisone	S	Unknown	40 Mg		Not Reported
Arava	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Salazopyrin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17729389	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436797			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Mefenamic Acid			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Tylenol /00020001/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17730576	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437119		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Leukopenia; Mouth Ulceration; Patient Dissatisfaction With Treatment	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Apo-Azathioprine	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17743411	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437155			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Sulfasalazine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Oral			Not Reported

	Apo-Prednisone	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17743416	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200437389		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17743421	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437443			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17743424	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200437159		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17743992	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437152		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Injection Site Reaction; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

	Hydroxychloroquine Sulfate		C	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17744189	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436841		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Sounds Abnormal; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported
	Alprazolam			C	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Asa			C				Not Reported
	Bisoprolol Fumarate			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Paroxetine			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Risedronate			C	Unknown			Not Reported

Simvastatin	C	Unknown	Not Reported
Statex /00036302/	C	Unknown	Not Reported
Telmisartan	C	Unknown	Not Reported
Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17747073	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437411			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Goitre; Headache; Inflammation; Joint Swelling; Knee Arthroplasty; Lower Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Citalopram Hydrobromide			C	Unknown			Not Reported
	Ketoprofen			C				Not Reported
	Naproxen			C				Not Reported
	Omeprazole			C				Not Reported
	Prednisone			C	Oral			Not Reported

	Prednisone	C	Unknown	Not Reported
	Rosuvastatin Calcium	C		Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17747079	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20200437399		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disability; Drug Ineffective; Hepatic Enzyme Increased; Ileostomy; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapy Non-Responder; Wheelchair User	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17747149	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200437147		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Joint	Remicade			S	Intravenous (not otherwise specified)			Janssen

Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Actemra	S	Unknown		Not Reported
	Anakinra	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Rituximab	C	Unknown		Not Reported
	Canakinumab	C	Subcutaneous	Powder For Solution	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17747156	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437151		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Chronic Kidney Disease; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Azathioprine			S	Unknown			Not Reported
	Ciprofloxacin Hydrochloride			S	Unknown			Not Reported
	Clavulin /00756801/			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Mycophenolate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Plaquenil /00072603/	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17747157	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437139		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown			Not Reported
	Advil /00109201/			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac /01001802/			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17747993	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200437162		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Rash; Rheumatoid Arthritis; Urticaria	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Cefazolin			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Amlodipine			C				Not Reported
	Benadryl /00000402/			C				Not Reported
	Arava			C				Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C				Not Reported
	Tofacitinib Citrate			C	Unknown			Not Reported
	Viread			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17751807	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010411			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex

Of Consciousness; Rheumatoid Arthritis; Vomiting	Hydroxychloroquine	S	Unknown	400 Mg, Unk		Apotex
	Actemra	S	Unknown	8 Mg, Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Methotrexate	S	Unknown	20 Mg, Qd		Not Reported
	Orencia	S	Unknown	750 Mg, Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Meloxicam	C	Unknown	Unk		Not Reported
	Sulfasalazine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17757930	EXPEDITED (15-DAY)		LT, OT	JP-BAUSCH-BL-2020-013339		41 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Normal Newborn; Placenta Accreta	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown	Increased Dose		Not Reported
	Estradiol			S	Transdermal	Until 10 Weeks Of Gestation		Not Reported
	Tacrolimus Hydrate			S	Unknown			Not Reported
	Progesterone			S	Vaginal	Until 10 Weeks Of Gestation		Not Reported
	Dydrogesterone			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Oxytocin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17773117	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2020-023950		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Haematoma; Purpura; Thrombocytopenia	Azithromycin	S	Oral	Unk	Aurobindo
	Cefotaxime	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Inexium	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Norepinephrine	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Lovenox	S	Subcutaneous	Unk	Not Reported
	Loxen (Nicardipine Hydrochloride)	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Sufentanil	C	Unknown	Unk	Not Reported
	Nimbex	C	Unknown	Unk	Not Reported
	Hypnovel	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17773297	EXPEDITED (15-DAY)		DE, OT	MX-ADVANZ PHARMA-202004004918			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		200 Mg, Bid		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Norepinephrine			C		Unk		Not Reported
	Ceftazidime			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Trimethropim Sulfamethoxazole			C		Unk		Not Reported
	Lineozlid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17773444	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595675		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Cough; Drug Ineffective; Gait Disturbance; Gait Inability; Hypoaesthesia; Joint Swelling; Musculoskeletal Pain; Neck Pain; Peripheral Swelling; Pharyngeal Oedema; Rash; Therapeutic Product Effect Decreased	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Celebrex	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17773503	EXPEDITED (15-DAY)		DE, OT	MX-ADVANZ PHARMA-202003004282			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17773686	EXPEDITED (15-DAY)		DE, HO	CN-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-245681		37 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Histoplasmosis Disseminated; Respiratory Failure	Hydroxychloroquine			S	Oral	Unk		Sun
	Methylprednisolone			S	Unknown	200 Milligram, Daily		Not Reported
	Prednisone			S	Unknown	40 Milligram, Daily		Mutual

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17773712	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-024314		62 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Hypocoagulable State; Hypofibrinogenaemia; Thrombocytopenia	Azithromycin			S	Oral	500 Milligram, Dia		Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Milligram, Once A Day		Not Reported
	Enoxaparin			S	Subcutaneous	80 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Roactemra			S	Intravenous (not otherwise specified)	600 Milligram 1 Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17773717	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595963		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

	Enbrel	S	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Wellbutrin	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17773731	EXPEDITED (15-DAY)		DE	ES-AUROBINDO-AUR-APL-2020-024369		26 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Dexketoprofen			S	Intravenous (not otherwise specified)	25 Milligram, 3 Times A Day		Not Reported
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Milligram, Once A Day		Not Reported
	Enoxaparin			S	Subcutaneous	40 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram, Total		Not Reported
	Tocilizumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17773862	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595816			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17773884	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596145		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous drip			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Acetaminophen			C				Not Reported
	Codeine			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17773971	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-246369		82 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	500 Milligrams, Daily		Sun
	Teicoplanin			S	Intravenous (not otherwise specified)	400 Milligram, Daily		Not Reported
	Plaquenil			S	Oral	600 Milligrams, Daily		Not Reported
	Haloperidol			S	Oral	5 Gtt Drops, Daily		Not Reported
	Haloperidol			S	Oral	5 Gtt Drops		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17774143	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596655			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Ill-Defined Disorder; Malaise; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17774166	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-001325			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Nausea	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Ipca
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Ipca
	Fluoxetine			C	Unknown	1 Dosage Form, Qd		Not Reported
	Levothyroxine			C	Unknown	1 Dosage Form, Qd		Not Reported
	Cerazette			C	Unknown	1 Dosage Form, Qd		Not Reported
	Colecalciferol			C	Unknown	1 Dosage Form, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17774196	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595905		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Arthralgia; Bronchitis; C-Reactive Protein Increased; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspepsia; Fear; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Desoximetasone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17774317	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596306		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17774396	EXPEDITED (15-DAY)		OT	PHHY2019DE192157			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conjunctivitis Bacterial; Conjunctivitis Bacterial; Contusion; Cystitis; Diarrhoea; Fall; Myalgia; Respiratory Tract Infection; Respiratory Tract Infection; Rhinitis; Sinusitis	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis
	Abatacept			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17774409	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201709-005235			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Oral	400 Mg		Concordia
	Hydroxychloroquine			S	Unknown	400 Mg		Concordia
	Methotrexate			S	Unknown	25 Mg, Weekly		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported
	Adalimumab			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17774424	EXPEDITED (15-DAY)		HO	ES-BAUSCH-BL-2020-013591		45 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatitis	Doxiciclina	S	Oral		Not Reported
	Doxiciclina	S			Not Reported
	Azitromicina	S	Oral		Not Reported
	Azitromicina	S			Not Reported
	Hidroxicloroquina	S	Oral		Not Reported
	Hidroxicloroquina	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17774466	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2020-ES-1233693		56 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hypoacusis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17774467	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1233697		57 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Roactemra			S	Intravenous (not otherwise specified)			Not Reported
	Roactemra			S				Not Reported
	Lopinavir/Ritonavir			S	Oral	4 Dosage Forms Daily;		Not Reported
	Lopinavir/Ritonavir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17774537	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597691			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Product Use In Unapproved Indication; Therapeutic Product Effect Decreased	Actemra		S	Unknown		Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Cimzia		S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Xeljanz		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17774847	EXPEDITED (15-DAY)		DS	CA-ROCHE-2595829		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Subcutaneous			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Salazopyrin	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Actemra	C	Unknown	Not Reported
	Arava	C	Oral	Not Reported
	Bifidobacterium Bifidum	C		Not Reported
	Celebrex	C	Unknown	Not Reported
	Loperamide	C		Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Pantoprazole	C		Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Simponi	C		Not Reported
	Sulfasalazine	C		Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17775254	EXPEDITED (15-DAY)		HO, LT, OT	CA-ADVANZ PHARMA-GSH201706-003681			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Hydroxychloroquine	S	Unknown	Unk	Concordia
	Hydroxychloroquine	S	Unknown	Unk	Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Unknown	Unk	Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Unknown	400 Mg	Concordia
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S			Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Oxycodone	S	Unknown	10 Mg, Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported

Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S	Unknown	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Enbrel	S	Subcutaneous	Unk		Not Reported
Enbrel	S	Unknown	Unk		Not Reported
Marijuana	S	Unknown	Unk		Not Reported
Xeljanz	S	Oral	Unk	Unk, Bid	Not Reported
Gold	S	Unknown	Unk		Not Reported
Ilaris	S	Subcutaneous	Unk		Not Reported
Ilaris	S	Subcutaneous	Unk		Not Reported
Ilaris	C				Not Reported
Methotrexate	C				Not Reported
Hydroxychloroquine Phosphate	C		Unk		Not Reported
Rituximab	C				Not Reported
Anakinra	C				Not Reported
Lyrica	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17775772	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593600		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Lupus-	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Tuberculin Test Positive	Celecoxib	S	Oral	Not Reported
	Celecoxib	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Toradol	S	Unknown	Not Reported
	Tramadol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17776951	EXPEDITED (15-DAY)		HO, LT	SI-ACCORD-181639		48 YR	Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Thrombocytopenia; Thrombocytopenia	Hydroxychloroquine			S	Oral	Strength: 200 Mg		Not Reported
	Kaletra			S	Oral	(80mg+20mg)/Ml Oral Solution, Dose 400mg/100 Mg		Not Reported
	Piperacillin Sodium/Tazobactam Sodium			C				Not Reported
	Esmeron			C				Not Reported
	Metoclopramide			C				Not Reported
	Analgin			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17777085	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598364			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported

Erythematosus	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17777086	EXPEDITED (15-DAY)		LT	CA-ROCHE-2598053			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Perforation; Joint Swelling; Therapeutic Product Ineffective; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17777448	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-GSH201902-000277			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Coronary Artery Occlusion; Herpes Zoster; Mobility Decreased; Osteoporosis; Spinal Fracture	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Plavix			S	Unknown	Unk		Not Reported
	Famotidine			S	Unknown	Unk		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported
	Doxycycline			S	Unknown	Unk		Not Reported
	Trandolapril			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Furosemide			S	Unknown	Unk		Not Reported
	Nifedipine			S	Unknown	Unk		Not Reported
	Loperamide			S	Unknown	Unk		Not Reported
	Ambien			S	Unknown	Unk		Not Reported
	Gabapentin			S	Unknown	Unk		Not Reported
	Nexium			S	Unknown	Unk		Not Reported
	Crestor			S	Unknown	Unk		Not Reported
	Potassium Acetate			S	Unknown	Unk		Not Reported
	Glyceryl Trinitrate			S	Unknown	Unk		Not Reported
	Victoza			S	Unknown	Unk		Not Reported
	Humira 40 Mg/0.8 Ml			S	Subcutaneous	40 Mg, Qod		Not Reported
	Humira 40 Mg/0.8 Ml			S	Subcutaneous	40 Mg,Qow		Not Reported
	Humira 40 Mg/0.8 Ml			S				Not Reported
	Flomax			S	Unknown	Unk		Not Reported
	Reglan			S	Unknown	Unk		Not Reported
	Trazodone			S	Unknown	Unk		Not Reported
	Imdur			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17777683	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235485			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Prednisone	S	Unknown	Actavis
	Methotrexate	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17777786	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235410		30 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Gait Inability; Movement Disorder; Nausea; Pain; Weight Increased	Prednisone			S	Unknown			Actavis
	Cymbalta			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17778059	EXPEDITED (15-DAY)		LT	CA-ROCHE-2598054			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Meningitis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Visual Impairment	Actemra			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Indometacin			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

	Naprosyn [Naproxen]	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17778115	EXPEDITED (15-DAY)		OT	FR-APPCO PHARMA LLC-2083741		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17778149	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200505935		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Ankle Arthroplasty; Arthralgia; Drug Ineffective; Hip Arthroplasty; Knee Arthroplasty; Pain In Extremity; Peripheral Swelling; Psoriasis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Gold (198 Au)			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17778165	EXPEDITED (15-DAY)		OT	FR-APPCO PHARMA LLC-2083742		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17778290	EXPEDITED (15-DAY)		DE, HO	ES-PFIZER INC-2020185611		70 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Bundle Branch Block Right; Hypertension; Hypofibrinogenaemia; Off Label Use; Pneumonia Escherichia; Product Use In Unapproved Indication; Ventricular Tachycardia	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Daily		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Single		Not Reported
	Tocilizumab			S				Not Reported
	Tocilizumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17778335	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593495		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone			S	Oral			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported

Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Desoximetasone	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Oral	Not Reported
	Fosamax	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Golimumab	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not	Not Reported

			otherwise specified)	
	Sarilumab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Topicort [Desoximetasone]	S	Subcutaneous	Not Reported
	Topicort [Desoximetasone]	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Tofacitinib Citrate	C	Unknown	Not Reported
	Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C		Not Reported
	Salazopyrin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17778359	EXPEDITED (15-DAY)		HO, OT	MX-APPCO PHARMA LLC-2083743		29 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nocardiosis	Hydroxychloroquine Sulfate			S	Oral			Appco Pharma
	Prednisone			S	Oral			Not Reported
	Mycophenolate Mofetil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17778367	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2020SE60059		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Purpura; Thrombocytopenia	Inexium			S	Intravenous (not otherwise specified)			Astrazeneca
	Cefotaxime Base			S	Intravenous (not			Not Reported

			otherwise specified)	
	Azithromycine Anhydrous	S	Oral	Not Reported
	Noradrenaline	S	Intravenous (not otherwise specified)	Not Reported
	Lovenox	S	Subcutaneous	Not Reported
	Loxen [Nicardipine Hydrochloride]	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Oral	Not Reported
	Sufentanil	C		Not Reported
	Nimbex	C		Not Reported
	Hypnovel	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17778446	EXPEDITED (15-DAY)		DE, OT	FR-MYLANLABS-2020M1046089			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Intentional Product Misuse; Off Label Use	Azithromycin			S		Unk		Not Reported
	Plaquenil /00072603/			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17778478	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235393			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Pre- Filled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Reactine [Cetirizine]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17778499	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235252			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Alendronate Sodium			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17778602	EXPEDITED (15-DAY)		OT	DE-APPCO PHARMA LLC-2083745		21 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemophagocytic Lymphohistiocytosis; Withdrawal Syndrome	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Prednisolone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17778628	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1233508		45 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Mg		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Doxiciclina (1395a)			S	Oral	100 Mg		Not Reported
	Doxiciclina (1395a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17778629	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1233662		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Hidroxicloroquina (2143a)			S	Oral	400 Mg		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Roactemra			C	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Roactemra			C				Not Reported
	Ceftriaxona (501a)			C	Intravenous (not otherwise specified)	2 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17779027	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597533			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Red Blood Cell Sedimentation Rate Increased; Urticaria	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Cimzia			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Therapy Duration: 486.0		Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			C	Parenteral			Not Reported
	Azathioprine			C	Unknown	1 Every 1 Days		Not Reported
	Ciclosporin			C				Not Reported
	Minocycline			C				Not Reported
	Penicillamine			C				Not Reported
	Phenylbutazone			C				Not Reported
	Prednisolone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tofacitinib			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17779230	EXPEDITED (15-DAY)		HO	CA-ROCHE-2593246		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Meningitis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17779962	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2020189648		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Gastrointestinal Haemorrhage; Hepatitis Acute; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Enoxaparin			S	Subcutaneous	60 Mg, 2x/Day (Every 12 Hours)		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Total		Not Reported
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Mg, 1x/Day For 6 Days		Not Reported
	Dexamethasone			S	Intravenous (not otherwise specified)	10 Mg, 1x/Day For 5 Days		Not Reported
	Dexamethasone			S	Intravenous (not otherwise specified)	5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17780263	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235392		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Risedronate Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17780732	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1046150		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Bisoprolol			S		1.25 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17780744	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1046103			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Discomfort; Intentional Product Misuse; Loss Of Consciousness; Off Label Use; Product Use In Unapproved Indication; Ventricular Arrhythmia	Azithromycin	S	Unk		Not Reported
	Plaquenil /00072603/	S	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17780745	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1046106			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation; Intentional Product Misuse; Off Label Use	Azithromycin			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17780884	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1046101			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Intentional Product Misuse; Off Label Use	Azithromycin			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17780898	EXPEDITED (15-DAY)		LT	FR-MYLANLABS-2020M1046072		56 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Olanzapine			S	Oral	7.5 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	800 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17782760	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1045950		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Condition Aggravated; Hepatocellular Injury	Azithromycin			S	Oral	250 Milligram, Qd		Not Reported
	Plaquenil /00072602/			S	Oral	600 Milligram, Qd		Mylan
	Rocephine			S	Oral	2 Gram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17784090	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436771			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Neutropenia	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran /00001501/			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	11271558	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1606866		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hepatic Enzyme Increased; Hypertension; Joint Swelling; Loss Of Consciousness; Loss Of	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Unknown	40 Mg, Unk 3/C G2		Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

Personal Independence In Daily Activities; Mobility Decreased; Pneumonia; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Tocilizumab	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	12688972	EXPEDITED (15-DAY)		OT	CA-ROCHE-1675763			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Arthralgia; Bronchitis; C-Reactive Protein Increased; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Ineffective; Drug Intolerance; Dyspepsia; Fear; Joint Swelling; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Abatacept	S	Unknown	Not Reported
	Cortisone	C	Oral	Not Reported
	Desoximetasone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	12856089	EXPEDITED (15-DAY)		OT	CA-ROCHE-1712817			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculin Test Positive	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Discontinued Due To A Side Effect For 2 Years		Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous	Discontinued Due To Developing Cancer		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Taken For 2 Years, Stopped Working		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Stopped Working Therapy Duration: 730 Days		Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Amoxicillin;Clavulanate Potassium	C		Not Reported
Amoxil [Amoxicillin]	C		Not Reported
Adalimumab	C		Not Reported
Bcg Vaccine	C	Intravenous (not otherwise specified)	Not Reported
Bcg Vaccine	C	Intravenous (not otherwise specified)	Not Reported
Bcg Vaccine	C	Unknown	Not Reported
Amoxicillin	C		Not Reported
Amoxicillin Trihydrate;Clavulanate Potassium	C	Unknown	Not Reported
Amoxil [Amoxicillin]	C	Unknown	Not Reported
Amoxillat	C		Not Reported
Gold	C	Unknown	Not Reported
Hydroxychloroquine	C	Subcutaneous	Not Reported
Risedronate	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	14535544	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0125		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Oral Mucosal	Kineret			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Methotrexate Sodium	S	Oral	Dose: 12.5 Mg Once Daily	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous	Dose. 12.5 Mg 1x1 Daily	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg Daily	Not Reported
	Methotrexate	S	Oral	12.5 Milligram	Not Reported
	Methotrexate Sodium	S	Oral	Dose: 12.5 Mg	Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	15568769	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1700		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Product Use Issue	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

	Enbrel	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Oral	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	16499902	EXPEDITED (15-DAY)		OT	CA-SA-2019SA170806			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Arava			S	Oral	20 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Prednisone			S	Oral	5 Mg		Not Reported
	Sulfasalazine			S	Unknown	1000 G, Bid		Not Reported
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Unknown	20 Mg		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	16645869	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202544			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Sanofi
	Arava			S		200 Mg, Qd		Sanofi
	Methotrexate			S	Oral	175 Mg, Qw		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	16651228	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202829			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Hydroxychloroquine			S		400 Mg		Sanofi
	Methotrexate			S		20 Mg, Qd		Not Reported
	Leflunomide			S		20 Mg		Sanofi
	Enbrel			S				Not Reported
	Actemra			S		8 Mg		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S		750 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	16945913	EXPEDITED (15-DAY)		OT	CA-ROCHE-2437307			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Depo-Medrol			C	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	16969607	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20191008623		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Adverse Event; Adverse	Otezla			S	Oral			Celgene
	Actemra			S	Unknown			Not Reported

Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Sleep Disorder	Apo-Leflunomide	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Unknown		Not Reported
	Minocin	S	Unknown		Not Reported
	Minocycline	S	Unknown		Not Reported
	Myochrysine	S	Subcutaneous		Not Reported
	Myochrysine	S	Parenteral		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Orencia	S	Unknown	250 Milligram	Not Reported
	Rituximab	S	Parenteral		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sirukumab	S	Unknown		Not Reported
	Tofacitinib Citrate	S	Oral	10 Milligram	Not Reported
	Ustekinumab	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral	10 Milligram	Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Stelara	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Salazopyrin	S	Unknown		Not Reported
	Methotrexate	C	Unknown	15 Milligram	Not Reported
	Methotrexate	C	Unknown	15 Milligram	Not Reported
	Prednisone	C	Unknown	5 Milligram	Not Reported
	Rheumatrex	C	Unknown		Not Reported

	Rheumatrex		C	Unknown	15 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17019418	EXPEDITED (15-DAY)		HO	CA-ROCHE-2458073			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Intentional Product Use Issue; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Rituximab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17036319	EXPEDITED (15-DAY)		OT	CA-ROCHE-2462412			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Meloxicam			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Sulfasalazine	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17221720	EXPEDITED (15-DAY)		HO	CA-ROCHE-2456725			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gammagard			S	Intravenous (not otherwise specified)	Liquid Also Know As Immune Globulin (Human)		Not Reported
	Gammagard			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Other			Not Reported

	Triamcinolone	S	Intra-articular	Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Not Reported
	Naproxen	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17261070	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514041			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution For Injection		Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)	
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17402847	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2020058662		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Drug Withdrawal Syndrome; Hypoaesthesia; Pain; Paraesthesia	Lyrica			S		200 Mg		Pfizer
	Lyrica			S		"300 Mg Twice"		Pfizer
	Sildenafil Citrate			S		"20 Mg Three Times"		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		"200 Mg Twice"		Not Reported
	Trazodone			S		"100 Mg Once"		Not Reported
	Trazodone			S				Not Reported
	Atorvastatin			C		Unk		Not Reported
	Eliquis			C		Unk		Not Reported
	Klor-Con			C		Unk		Not Reported
	Lexapro			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17420592	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0792		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Kineret			S	Unknown			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17433728	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2019025070			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis;	Sildenafil			S	Unknown	60 Milligram, Qd		Macleods
	Sildenafil			S	Unknown	30 Milligram, Qd, Film		Macleods

Oedema Peripheral; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment				Coated Tablet	
	Omeprazole 20 Mg	S	Oral	40 Milligram, Qd, 1 Df. 20 Mg Bid	Not Reported
	Omeprazole 20 Mg	S	Oral	20 Milligram, Qd, 1 Df	Not Reported
	Ramipril	S	Oral	2.5 Milligram, Qd, 2 Df	Not Reported
	Ramipril	S	Unknown	5 Milligram, Qd	Not Reported
	Ramipril	S	Oral	1 Dosage Form, Bid	Not Reported
	Lyrica	S	Unknown	100 Milligram, Tid, 300 Mg Qd, 1 Df, Tid	Not Reported
	Lyrica	S	Unknown	100 Milligram, Tid, 300 Mg Qd, 1 Df, Tid	Not Reported
	Volibris	S	Oral	30 Milligram, Bid	Not Reported
	Volibris	S	Oral	30 Milligram, Qd	Not Reported
	Volibris	S	Oral	30 Milligram, Qd	Not Reported
	Volibris	S	Oral	30 Milligram, Qd	Not Reported
	Roactemra	S	Subcutaneous	162 Milligram, Q.W. (Solution For Injection In Pre-Filled Syringe)	Not Reported
	Roactemra	S	Subcutaneous	162 Milligram, Q.W. (Solution For Injection In Pre-Filled Syringe)	Not Reported
	Quensyl	S	Unknown	40 Milligram, Bid	Not Reported
	Quensyl	S	Unknown	1 Dosage Form, Bid (1-0-0), 20 Mg	Not Reported
	Eliquis	S	Unknown	5 Milligram, Qd, 2 Df Qd, 2.5 Mg Bid	Not Reported
	Eliquis	S	Unknown	1 Dosage Form, Bid	Not Reported
	Spasmolyt	S	Unknown	1 Dosage Form, Bid ((1-0-1))	Not Reported
	Spasmolyt	S	Unknown	30 Milligram, Qd (0 -0 -1)	Not Reported
	Spasmolyt	S	Unknown	1 Dosage Form, Qd	Not Reported
	Spasmolyt	S	Unknown	15 Milligram, Qd	Not Reported

Ambrisentan	S	Unknown	30 Milligram, Qd		Not Reported
Ambrisentan	S	Unknown	30 Milligram, Qd		Not Reported
Ambrisentan	S	Unknown	1 Dosage Form, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17557582	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200318930		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Dermatitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gallbladder Disorder; Groin Pain; Pancreatitis; Photosensitivity Reaction; Rheumatoid Arthritis; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Citalopram			C				Not Reported
	Prednisolone			C				Not Reported
	Gold			C	Unknown			Not Reported
	Pantoloc /01263201/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17697006	EXPEDITED (15-DAY)		DE, OT	FR-ADVANZ PHARMA-202004003543			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Multiple Organ Dysfunction Syndrome; Off Label Use; Pneumonia Bacterial	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd, (Film Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	1000 Mg, Qd, (Film Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd, (Film Coated Tablet)		Concordia
	Ceftriaxone			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Rifamycine [Rifamycin]			C		Unk		Not Reported
	Carbomere			C		Unk		Not Reported
	Metoclopramide			C		Unk		Not Reported
	Vitamin A [Retinol]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17721926	EXPEDITED (15-DAY)		OT	RU-ADVANZ PHARMA-202004003973			Unknown	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Pressure Fluctuation; Diarrhoea; Dizziness; Off Label Use; Pneumonia; Pyrexia	Hydroxychloroquine			S	Oral	400 Mg, Bid		Concordia
	Hydroxychloroquine			S	Oral	200 Mg, Bid (Maintaining Dose)		Concordia
	Kaletra			S	Unknown	400 Mg, Bid (Q12h)		Not Reported
	Azithromycin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17742406	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1229778		96 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Extrasystoles; Off Label Use	Azithromycin			S	Unknown	500 Mg		Not Reported
	Plaquenil			S	Unknown	400 Mg		Not Reported
	Lasix 25 Mg Compresse			C				Not Reported
	Novorapid			C				Not Reported
	Normix			C				Not Reported
	Dobetin			C				Not Reported
	Lantus			C				Not Reported
	Movicol			C				Not Reported
	Deltacortene 25 Mg Compresse			C				Not Reported
	Pantorc 20 Mg Compresse Gastroresistenti			C				Not Reported
	Cardirene 75 Mg			C				Not Reported
	Metoprololo			C		50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17752357	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1044783		82 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Teicoplanin			S	Intravenous (not otherwise specified)	400 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	600 Milligram, Qd		Mylan
	Haloperidol			S	Oral	5 Gtt Drops, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17752431	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010539		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Gait	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Unknown	200 Mg, Q.O.Wk.		Not Reported

Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Certolizumab Pegol	S	Subcutaneous	200 Mg, Q.O.Wk.		Not Reported
	Certolizumab Pegol	S	Subcutaneous	200 Mg, Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Methylprednisolone	S	Unknown	80 Mg, Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Plaquenil /00072602/	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Xeljanz	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	400 Mg, Unk, 1 Every 8 Weeks		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	400 Mg, Unk		Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Q.Wk.		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Etanercept	S	Unknown	Unk		Not Reported
	Naproxen	C	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported
	Rituxan	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17772419	EXPEDITED (15-DAY)		DE, OT	IT-INCYTE CORPORATION-2020IN004123			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Cardiac Arrest; Multiple Organ Dysfunction Syndrome; Respiratory Failure; Sepsis	Inc424			S	Oral	5 Mg, Bid		Incyte
	Inc424			S				Incyte
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	1 Df, Bid		Not Reported
	Prezista			S	Unknown	800 Mg, Qd		Not Reported
	Clexane			S	Unknown	0.6 Ml, Qd (6 Syringe)		Not Reported
	Rocefin			S	Intramuscular	2 G, Qd (1 Bottle)		Not Reported

Plasil [Metoclopramide Hydrochloride]	C	Intravenous (not otherwise specified)	1 Df, Qd (Inet 5f 2 Ml)	Not Reported
Albumine Baxter	C	Intravenous (not otherwise specified)	50 G/Ml, Qd (1 Fl, 250 Ml)	Not Reported
Antra [Omeprazole Magnesium]	C	Intravenous (not otherwise specified)	40 Mg, Qd (Infus, 1 Fl)	Not Reported
Noradrenalina [Norepinephrine Hydrochloride]	C	Intravenous (not otherwise specified)	4 Ml/H (10 F)	Not Reported
Ringers Lactate	C	Intravenous (not otherwise specified)	500 Mg, Qd	Not Reported
Tazocin	C	Intravenous (not otherwise specified)	12 Fl (4g+0.500g), Qd	Not Reported
Oxepa	C	Intravenous (not otherwise specified)	40 Ml/H	Not Reported
Fluimucil	C	Respiratory (inhalation)	1 Df, Qd (Aer, 10f)	Not Reported
Vici	C	Intramuscular	1 Df, Qd (5f)	Not Reported
Eutirox	C	Oral	1 Df, Qd (500cpr, 125 Mcg)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17778385	EXPEDITED (15-DAY)		OT	RO-AUROBINDO-AUR-APL-2020-024106			Male	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pneumonia; Sars-Cov-2 Test Positive	Azithromycin			S	Unknown	Unk		Aurobindo
	Kaletra			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17778542	EXPEDITED (15-DAY)		HO, LT, OT	FR-CELLTRION INC.-2020FR022184			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Respiratory Distress Syndrome; Coronavirus Infection; Cough; Headache; Interstitial Lung Disease; Lung Opacity; Myalgia; Off Label Use; Pyrexia; Respiratory Failure; Therapeutic Response Unexpected	Rituximab (Unknown)	S	Intravenous (not otherwise specified)	Four Infusions (375 Mg/M2) Were Weekly	Not Reported
	Rituximab (Unknown)	S		Maintenance Therapy; 500 Mg	Not Reported
	Prednisone	S	Unknown	15 Mg Daily	Not Reported
	Hydroxychloroquine Sulfate	S		200 Mg/8 Hour For 10 Days From Day #19	Not Reported
	Nebivolol	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17778681	EXPEDITED (15-DAY)		HO	CA-ROCHE-2596430		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Allergic Oedema; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Infection; Joint Surgery; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty; Urticaria	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral	Therapy Duration: 2.0 Months		Not Reported
	Methotrexate			S	Subcutaneous	Therapy Duration: 2.0 Months		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Therapy Duration: 2.0 Months		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Viread			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17778789	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247120		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Metamizol (111a)			S	Intravenous (not otherwise specified)	2 Gram, Every 6 Hours		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram, Daily		Not Reported
	Paracetamol (12a)			S	Intravenous (not otherwise specified)	1 Gram, Tid		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg ; In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17778804	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247111		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg ; In Total		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17779033	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2597012		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Ill-Defined	Rituximab			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported

Disorder; Infection; Kidney Infection; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Sepsis; Therapeutic Response Decreased	Enbrel		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Methotrexate		S	Oral		Not Reported
	Methotrexate		S	Oral	4.0 Dosage Forms	Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17779152	EXPEDITED (15-DAY)		OT	CA-ROCHE-1832233		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Rituxan	S	Intravenous drip	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Actemra	C	Unknown	Not Reported
	Sodium Aurothiomalate	C		Not Reported
	Xeljanz	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17779175	EXPEDITED (15-DAY)		HO	CA-ROCHE-2595777		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty; Urticaria	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17779238	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247037		78 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	500 Milligrams, Daily		Sun
	Plaquenil			S	Oral	600 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17779329	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-037950		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Intentional Product Use Issue	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17779338	EXPEDITED (15-DAY)		DE	CA-ROCHE-2597863			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported

Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Anakinra	S	Unknown	Not Reported
Anakinra	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Ilaris	S	Subcutaneous	Not Reported
Ilaris	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17779347	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2020079500		30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ill-Defined Disorder	Benlysta Solution For Infusion			S	Unknown	Unk		Glaxosmithkline

	Plaquenil	S	Unknown	Unk	Not Reported
	Cellcept	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17779405	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005272			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Corneal Degeneration	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17780060	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245719		77 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Thrombocytopenia	Azithromycin			S	Oral	500 Milligrams, Daily		Sun
	Clexane			S	Subcutaneous	4 Kilo-International Unit, Daily		Not Reported
	Clexane			S				Not Reported
	Plaquenil			S	Oral	600 Milligrams, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17780114	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597489		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17780165	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1233663		57 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Mg		Teva
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg Day		Not Reported
	Tocilizumab (8289a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17780193	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1233665		53 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Mg		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Enoxaparina (2482a)			S	Subcutaneous	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17780194	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1233691		27 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	800mg Day (Load) Followed 400 Mg Day		Teva
	Hidroxicloroquina (2143a)			S	Oral	400 Mg		Teva
	Ivermectina (7778a)			S	Oral	12 Mg Du		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not	600 Mg		Not Reported

					otherwise specified)					
	Tocilizumab (8289a)			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17780279	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247122		47 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Paracetamol			S	Oral	1 Gram, Tid		Ohm Lab
	Dexketoprofeno (7312a)			S	Intravenous (not otherwise specified)	25 Mg Cada 8 Horas		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram, Daily		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg ; In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17780317	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598582		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation; Off Label Use; Pneumonia; Pruritus; Rheumatoid Arthritis; Urosepsis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methyl Salicylate			S	Unknown			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17780345	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235248			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17780437	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594910		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance;	Amlodipine Besilate			S	Oral			Not Reported
	Amlodipine Besilate			S	Unknown			Not Reported
	Amlodipine Besilate			S	Oral			Not Reported
	Asacol			S	Unknown			Not Reported
	Diamicron			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Gliclazide	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Diphenhydramine	C		Not Reported
	Ebastine	C		Not Reported
	Ferrous Gluconate	C		Not Reported
	Folic Acid	C		Not Reported
	Methylprednisolone	C		Not Reported
	Rosuvastatin Calcium	C		Not Reported
	Tylenol	C		Not Reported
	Vitamin D3	C		Not Reported
	Acetaminophen	C		Not Reported
	Atacand Plus	C		Not Reported
	Bisoprolol Fumarate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17780482	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235418		67 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anorectal Discomfort; Arthralgia; Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Dyspepsia; Gait Inability; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Skin Hyperpigmentation; Treatment Failure	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Fentanyl			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17780489	EXPEDITED (15-DAY)		OT	CA-ROCHE-1865689		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Insomnia; Iodine Allergy; Off Label Use; Pain; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 4.0 Year(S)		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 3.0 Months		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Venlafaxine Hydrochloride			S	Oral	Every 1 Day(S)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydrodiuril			C	Unknown			Not Reported
	M-Eslon			C	Unknown	Capsule, Extended Release		Not Reported
	Statex [Morphine Sulfate]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17780500	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596647			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Infection; Joint Swelling; Liver Function Test Increased;	Rituximab			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Pain; Paralysis; Skin Infection; Treatment Failure; Urinary Tract Infection	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Acetaminophen	C	Oral	Not Reported
	Diphenhydramine	C	Oral	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Methylprednisolone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17780536	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597205			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17780665	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597998			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17781433	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593776			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased;	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Treatment Failure	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Tofacitinib Citrate		S	Unknown	Not Reported
	Leflunomide		C		Not Reported
	Sulfasalazine		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17782195	DIRECT	Y	OT			73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clinical Trial Participant; Hypoglycaemia; Product Use In Unapproved Indication; Therapy Interrupted	Hydroxychloroquine			S	Oral			Sandoz

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17782822	DIRECT	Y	DE			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Clinical Trial Participant; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral		9 DAY	Sandoz

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17782864	DIRECT	Y	DE			72 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Clinical Trial Participant; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral		0.93 DAY	Sandoz

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17782994	EXPEDITED (15-DAY)		OT	NVSC2020US128816			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Mycophenolate Mofetil			S	Transplacental	Unk		Novartis
	Prednisone			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Azathioprine			S	Transplacental	Unk		Not Reported
	Tacrolimus			S	Transplacental	Unk		Not Reported
	Lovenox			S	Transplacental	Unk		Not Reported
	Bactrim			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17782995	EXPEDITED (15-DAY)		HO, LT, OT	JP-ALVOGEN-2020-ALVOGEN-108377		41 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Disorder; Blood Pressure Increased; Caesarean Section; Hormone Level Abnormal; Hypogonadism; Infarction; Maternal Exposure During Pregnancy; Pelvic Infection; Placenta Accreta; Pre-Eclampsia; Proteinuria; Uterine Atony; Vaginal Haemorrhage	Estradiol			S	Transdermal			Not Reported
	Tacrolimus			S				Not Reported
	Progesterone			S	Vaginal			Not Reported
	Dydrogesterone			S	Oral			Not Reported
	Prednisolone			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17782998	DIRECT	Y	OT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Clinical Trial Participant; Hypoglycaemia; Product Use In Unapproved Indication	Hydroxychloroquine		S	Oral	5 DAY	Sandoz

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17783422	NON-EXPEDITED			US-PFIZER INC-2020192270		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Sulfasalazine			S				Pfizer
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17783531	NON-EXPEDITED			US-PFIZER INC-2020192170		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Azathioprine			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17783975	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1234425		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gamma-Glutamyltransferase Increased; Transaminases Increased	Azithromycine Anhydre			S	Oral			Not Reported
	Augmentin			S	Oral	3g		Not Reported
	Plaquenil			S	Oral	200 Mg X 3 Per Day		Not Reported
	Lovenox			S	Subcutaneous			Not Reported
	Acupan			C				Not Reported
	Lamictal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17784010	DIRECT	Y	OT			85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clinical Trial Participant; Hypoglycaemia; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral		6.42 DAY	Sandoz

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17784015	DIRECT	Y	DE			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Clinical Trial Participant; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral		1.02 DAY	Sandoz

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17784019	DIRECT	Y	OT			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clinical Trial Participant; Hypoglycaemia; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral		8.03 DAY	Sandoz

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17784026	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202004003912			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			C	Intravenous (not	500 Mg, Qd		Not Reported

			otherwise specified)			
	Dopamine	C		Low Dose		Not Reported
	Cardura	C	Oral	8 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17784110	EXPEDITED (15-DAY)		DE, OT	US-ADVANZ PHARMA-202005005124			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Drug Ineffective For Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17784210	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1234252		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17784713	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005093			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Hydroxychloroquine			S		Unk		Concordia
	Xeljanz Xr			S	Oral	11 Mg, Qd		Not Reported
	Methotrexate			S		Unk		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17784740	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1234253		49 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17784959	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020191445		45 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Azithromycin			S				Pfizer
	Doxycycline Hyclate			S	Oral	100 Mg, 2x/Day (100 Mg Every 12 Hours)		Pfizer
	Doxycycline Hyclate			S				Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day (400 Mg Day)		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785260	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1234538		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported

	Roactemra	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785273	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1234539		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Sulpirida (3076a)			S	Oral	150 Milligram Daily;		Not Reported
	Enoxaparina (2482a)			S	Subcutaneous	40 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785276	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1234791		45 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Enoxaparina (2482a)			S	Subcutaneous	40 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785357	EXPEDITED (15-DAY)		DE	ES-PFIZER INC-2020187763		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome; Off Label Use; Product Use In Unapproved Indication; Sudden Death	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Dolquine			S	Oral	400 Mg, 2x/Day		Not Reported
	Propofol			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Metoclopramid [Metoclopramide]			S	Intravenous (not otherwise specified)	10 Mg, 3x/Day		Not Reported
	Salbutamol			S	Respiratory (inhalation)	0.1 Mg, 4x/Day		Not Reported

Cefotaxim	C	Intravenous drip	4 G, 2x/Day		Not Reported
Enoxaparin Sodium	C	Subcutaneous	Unk		Not Reported
Tocilizumab	C	Intravenous (not otherwise specified)	600 Mg, 1x/Day		Not Reported
Midazolam	C	Intravenous drip	100 Mg, 1x/Day		Not Reported
Ipratropium Bromide	C	Respiratory (inhalation)	20 Ug, 4x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785416	EXPEDITED (15-DAY)		DE, HO	MX-ADVANZ PHARMA-202004005048			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased; Off Label Use; White Blood Cell Count Decreased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		1 Dosage Form, Bid		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Methylprednisolone			C				Not Reported
	Enoxaparin			C				Not Reported
	Lopinavir+ Ritonavir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785463	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202004003974			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785480	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2020-ES-1234785		48 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva

	Hidroxicloroquina (2143a)	S				Teva
	Colchicina (142a)	S	Oral	1 Milligram Daily;		Not Reported
	Roactemra	S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Roactemra	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785486	DIRECT	Y	OT			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clinical Trial Participant; Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral		9.81 DAY	Sandoz

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785489	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1234786		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg Day		Not Reported
	Tocilizumab (8289a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785505	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1234790		62 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Roactemra			S	Intravenous (not	600 Mg		Not Reported

			otherwise specified)			
	Roactemra	S				Not Reported
	Enoxaparina (2482a)	S	Subcutaneous	40 Milligram Daily;		Not Reported
	Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785508	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1048030		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cornea Verticillata	Hydroxychloroquine			S	Unknown	600 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	1200 Milligram, Qd, 21.9 Mg/Kg/Day		Not Reported
	Everolimus			C	Unknown	10 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785570	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1233969			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Prednisone			S	Oral			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2000 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785573	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1233979			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785593	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234261		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported

	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Topicort	S	Oral		Not Reported
	Topicort	S	Cutaneous		Not Reported
	Leflunomide	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785597	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234474			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Confusional State; Hepatic Steatosis; Infection; Memory Impairment; Nausea; Nightmare; Pain; Polymyalgia Rheumatica; Rheumatoid Arthritis; Visual Impairment	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Acetaminophen			C				Not Reported
	Macrobid [Calrithrromycin]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17786218	EXPEDITED (15-DAY)		DE, OT	ES-PFIZER INC-2020189472		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Atrial Flutter; Cardio-Respiratory Arrest; Off Label Use; Product Use In Unapproved Indication	Azithromycin		S	Oral	500 Mg, 1x/Day	Pfizer
	Tocilizumab		S	Intravenous (not otherwise specified)	600 Mg, Single	Not Reported
	Kaletra		S	Oral	2 Df, 2x/Day	Not Reported
	Kaletra		S			Not Reported
	Dolquine		S	Oral	400 Mg, 1x/Day	Not Reported
	Dolquine		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17786244	EXPEDITED (15-DAY)		HO	CA-ROCHE-2595760			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Allergic Oedema; Arthrodesis; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty; Urticaria	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral	Therapy Duration: 2.0 Months		Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Therapy Duration: 2.0 Months		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17786577	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR-1234629		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Purpura; Thrombocytopenia	Azithromycine Anhydre			S	Oral			Not Reported
	Cefotaxime Base			S	Intravenous (not otherwise specified)			Not Reported
	Inexium			S	Intravenous (not otherwise specified)			Not Reported
	Noradrenaline			S	Intravenous (not otherwise specified)			Not Reported
	Lovenox			S	Subcutaneous			Not Reported
	Loxen [Nicardipine Hydrochloride]			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sufentanil			C				Not Reported
	Nimbex			C				Not Reported
	Hypnovel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17786842	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004004609			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective For Unapproved Indication	Hydroxychloroquine			S				Concordia
	Azithromycin			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17786865	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1046344		96 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arrhythmia; Extrasystoles; Off Label Use	Azithromycin	S	500 Milligram, Qd	Not Reported
	Plaquenil /00072603/	S	400 Milligram, Qd	Mylan
	Lasix /00032601/	C	25 Milligram, Qd	Mylan
	Novorapid	C		Mylan
	Normix	C		Mylan
	Lantus	C		Mylan
	Movicol /01749801/	C		Mylan
	Deltacortene	C		Mylan
	Pantorc	C		Mylan
	Cardirene	C		Mylan
	Metoprololo	C	50 Milligram, Qd	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17787004	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2020189427		64 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholangiolitis; Hypertransaminasaemia; Off Label Use	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, 1x/Day		Not Reported
	Urbason Solub			C	Intravenous (not otherwise specified)	40 Mg		Not Reported
	Antra [Omeprazole]			C		Unk		Not Reported
	Clexane			C	Subcutaneous	4000 Kiu		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17787014	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1235520		83 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hyponatraemia	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram		Not Reported

	Symbicort Turbuhaler 160 Micrograms/4,5 Micrograms/Inhalacion Polvo	S	Respiratory (inhalation)	6 Dosage Forms Daily; 2-2-2	Not Reported
	Salbutamol	S	Respiratory (inhalation)	6 Dosage Forms Daily; 2-2-2 Inh	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17787015	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234918			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrotic Syndrome	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Mycophenolate Mofetil			S	Unknown			Teva
	Prednisone			S	Oral			Actavis
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17787017	EXPEDITED (15-DAY)		HO, OT	CA-CELGENEUS-CAN-20200503123			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anaphylactic Shock; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nausea; Renal Impairment; Synovitis	Otezla			S	Oral			Celgene
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	520 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17787018	EXPEDITED (15-DAY)		DS	CA-CELGENEUS-CAN-20200503119		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Otezla			S	Unknown	120 Milligram		Celgene
	Otezla			S				Celgene
	Otezla			S				Celgene
	Rituximab			S	Intravenous drip	2000 Milligram		Not Reported
	Alendronate Sodium			S	Unknown	70 Milligram		Not Reported
	Apo-Ibuprofen			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ibuprofen			S	Oral	600 Milligram		Not Reported
	Ibuprofen			S	Oral	600 Milligram		Not Reported
	Ibuprofen			S	Oral			Not Reported
	Infliximab			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown	17.5 Milligram		Not Reported
	Methotrexate			S	Unknown	12 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported

Methotrexate	S	Unknown	12.5 Milligram	Not Reported
Methotrexate	S	Unknown	70 Milligram	Not Reported
Methotrexate	S	Unknown	10 Milligram	Not Reported
Remicade	S	Intravenous drip		Not Reported
Simponi	S	Subcutaneous		Not Reported
Stelara	S	Subcutaneous		Not Reported
Sulfasalazine	S	Endocervical		Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Benadryl	C	Unknown		Not Reported
Colchicine	C	Oral		Not Reported
Dexilant	C	Unknown		Not Reported
Febuxostat	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Gravol	C	Unknown		Not Reported
Mogadon	C	Oral	5 Milligram	Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Prednisone	C	Unknown		Not Reported
Uloric	C	Unknown	160 Milligram	Not Reported
Xeljanz	C	Unknown		Not Reported
Oxycodone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17787599	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234249			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Demyelination; Dermatomyositis; Drug Ineffective; Drug Intolerance; Fatigue; Mental Disorder; Muscle	Mycophenolate Mofetil			S	Unknown	3 Milligram Daily;		Teva
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis

Injury; Myalgia; Off Label Use; Product Use In Unapproved Indication; Pruritus; Rash	Hydroxychloroquine Sulfate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17787750	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234894		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Humira			S	Unknown	20 Milligram Daily;		Not Reported
	Humira			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Actemra			S	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17787778	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235258		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling;	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported

Rheumatoid Arthritis	Enbrel		S	Subcutaneous		Not Reported
	Actemra		S	Unknown		Not Reported
	Arava		S	Unknown	20 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17787913	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1233963		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Erythema; Gastric Haemorrhage; Nephrolithiasis; Peripheral Swelling; Pneumonia; Pulmonary Fibrosis; Skin Haemorrhage; Skin Warm	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Procytox			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Gold			C	Unknown			Not Reported
	Levofloxacin			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Fentanyl			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17788063	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1046493		78 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Plaquenil /00072602/			S	Oral	600 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17788562	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1046609		47 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Azithromycin			S				Not Reported
	Paracetamol			S	Oral	1gr Cada 8h		Not Reported
	Dexketoprofeno /01363801/			S	Intravenous (not otherwise specified)	25 Mg Cada 8 Horas		Mylan
	Hidroxicloroquina /00072601/			S	Oral	400 Mg Dia		Mylan
	Hidroxicloroquina /00072601/			S				Mylan
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Mylan
	Tocilizumab			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17788601	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1046601		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Mylan
	Hidroxicloroquina /00072601/			S	Oral	400 Mg Dia		Mylan
	Hidroxicloroquina /00072601/			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17788615	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1046603		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Qd (500 Mg Dia)		Not Reported
	Azithromycin			S				Not Reported

Metamizol /06276701/	S	Intravenous (not otherwise specified)	2 Gram, Q6h (2gr Cada 6 Horas)		Mylan
Hidroxicloroquina /00072601/	S	Oral	400 Milligram, Qd (400 Mg Dia)		Mylan
Paracetamol	S	Intravenous (not otherwise specified)	1 Gram, Q8h (1gr Cada 8 Horas)		Mylan
Tocilizumab	S	Intravenous (not otherwise specified)	600 Milligram, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17790362	EXPEDITED (15-DAY)		OT	CA-009507513-2005CAN004538		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cerebrovascular Accident; Diverticular Perforation; Drug Hypersensitivity; Drug Intolerance; Insomnia; Joint Swelling; Knee Arthroplasty; Pain; Peripheral Swelling; Psoriasis; Psoriatic Arthropathy; Rash; Skin Reaction; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Fosamax			S	Unknown			Merck
	Actemra			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Calcium (Unspecified)			S	Unknown			Not Reported
	Fosinopril Sodium			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Formulation: Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Morphine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Synthroid			S	Unknown			Not Reported
	Tylenol			S	Unknown	Unk		Not Reported
	Tylenol			S	Unknown	Unk		Not Reported
	Vitamin D (Unspecified)			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17790410	DIRECT	Y	OT			78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clinical Trial Participant; Hypoglycaemia; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral		5.95 DAY	Sandoz

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17791142	EXPEDITED (15-DAY)		HO, OT	US-ACCORD-181309			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Torsade De Pointes	Hydroxychloroquine			S		Twice On Day 1, Then 400 Mg Daily On Days 2 Through 5		Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	12441101	EXPEDITED (15-DAY)		OT	CA-ROCHE-1768215		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Arthralgia; Chronic Sinusitis; Diarrhoea; Diverticulum; Drug Ineffective; Haemochromatosis; Impaired Work Ability; Irritable Bowel Syndrome; Joint Swelling; Nausea; Off Label Use; Osteoporosis; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Inflectra [Infliximab]			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Methotrexate		S	Unknown	Not Reported
	Arava		C	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	12715328	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-1825208		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Rheumatoid Arthritis; Sciatica; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)	6 Years		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Tylenol No.2			S	Unknown			Not Reported
	Ramipril			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

Codeine Phosphate	S	Unknown			Not Reported
Cosopt	C	Unknown			Not Reported
Acetaminophen;Codeine Phosphate	C	Unknown	As Required		Not Reported
Diphenhydramine	C	Oral			Not Reported
Hydroxychloroquine Phosphate	C	Oral			Not Reported
Meprobamate	C				Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)			Not Reported
Tylenol	C				Not Reported
Phosphoric Acid	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	12890986	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP013207		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Contraindicated Product Administered; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder;	Apo-Gabapentin			S	Oral	100 Mg, Bid		Apotex
	Apo-Fentanyl Matrix			S	Unknown	Unk		Aveva
	Celecoxib			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Sulfasalazin			S	Oral	2.5 G, Qd		Not Reported
	Sulfasalazin			S	Oral	500 Mg, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488 Mg, Q.M.T.		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Myochrysine			S	Intramuscular	50 Mg, Q.3w		Not Reported
	Orencia			S	Intravenous (not	750 Mg, Q.M.T.		Not Reported

Treatment Failure			otherwise specified)		
	Oxycontin	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
	Abatacept	S	Intravenous (not otherwise specified)	750 Mg, Q.M.T., 1 Every 1 Month	Not Reported
	Arava	S	Oral	20 Mg, Qd, 1 Every 1 Day	Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	1 Df, Prn	Not Reported
	Oxycodone Terephthalate	C	Unknown	Unk, 1.0 Dosage, As Required	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Q.M.T.	Not Reported
	Actonel	C	Unknown	36 Mg, Q.Wk.	Not Reported
	Calcium	C	Unknown	Unk	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	1 Df, Qd	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg, Qd	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	Unk Unk, Qd	Not Reported
	Ergocalciferol	C	Unknown	400 Iu, Qd	Not Reported
	Ergocalciferol	C	Unknown	400 Iu, Q.Wk.	Not Reported
	Esomeprazole Magnesium	C	Unknown	40 Mg, Bid	Not Reported
	Esomeprazole Magnesium	C	Unknown	400 Iu, Qd	Not Reported
	Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported
	Loperamide Hydrochloride	C	Unknown	2.5 Mg, Unk	Not Reported
	Nasonex	C	Nasal	2 Df, Bid	Not Reported
	Nasonex	C	Unknown	Unk, Bid	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Mg, Unk	Not Reported
	Perphenazine	C	Oral	10 Mg, Unk	Not Reported
	Omega-3 Fatty Acids	C	Unknown	1200 Mg, Bid	Not Reported
	Pantoprazole Magnesium	C	Unknown	40 Mg, Qd	Not Reported
	Prednisone	C	Unknown	5 Mg, Qd	Not Reported
	Trazodone Hydrochloride	C	Oral	50 Mg, Qd	Not Reported

Tylenol /00020001/	C	Oral	1000 Mg, Qd	Not Reported
Vitamin D /00107901/	C	Unknown	400 Unk, Unk	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
Docosahexaenoic Acid W/Eicosapentae/06850301/	C	Unknown	1200 Mg, Bid, 2 Every 1 Day	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Sodium Ascorbate	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported
Vitamin A /00056001/	C	Unknown	Unk	Not Reported
Vitamin B12 /00056201/	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	5 Mg, Unk	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Mg, Bid	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Vitamin C /00008001/	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	13028484	NON-EXPEDITED			US-PFIZER INC-2016577872		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Body Height Decreased; Diarrhoea; Dyspepsia; Eructation; Flatulence; Gastrooesophageal Reflux Disease; Malaise; Nervousness; Vomiting	Xeljanz Xr			S		11 Mg, 1x/Day		Pfizer
	Hydroxychloroquine			S		200 Mg, Daily		Not Reported
	Hydroxychloroquine			S		200 Mg, 2x/Day		Not Reported
	Pravastatin			C		20 Mg, 1x/Day		Not Reported
	Lisinopril			C		10 Mg, 1x/Day		Not Reported

	B6	C	100 Mg, Unk	Not Reported
	B6	C	100 Mg, Unk	Not Reported
	D3	C	1000 Iu, Unk	Not Reported
	Omeprazole	C	20 Mg, 1x/Day (In Morning)	Not Reported
	Docusate Sodium	C	100 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	13119773	EXPEDITED (15-DAY)		OT	CA-ROCHE-1880386		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Naprosyn [Naproxen]			C	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	13210436	EXPEDITED (15-DAY)		OT	US-SA-2016SA235895		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Malaise; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Walking Aid User	Arava			S	Oral	20 Mg,Qd		Sanofi
	Plaquenil			S	Oral	400 Mg,Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg,Qd		Sanofi
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz			S	Oral	5 Mg,Bid		Not Reported
	Sulfasalazine			S	Unknown	500 Mg,Bid		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg,Qw		Not Reported
	Prednisone			S	Unknown	Unk Unk,Unk		Not Reported
	Prednisone			S	Unknown	5 Mg,Qd		Not Reported
	Rituxan			S	Unknown	Unk Unk,Unk		Not Reported
	Rituxan			S	Unknown	Unk Unk,Unk		Not Reported
	Infliximab			S	Unknown	300 Mg,Qd		Not Reported
	Pantoprazole			C	Unknown	Unk Unk,Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Atorvastatin			C	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	13271290	EXPEDITED (15-DAY)		DS	CA-ROCHE-1898441		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Arthropathy; Asthenia; C-Reactive Protein Increased;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Cataract; Constipation; Contraindicated Product Administered; Drug Ineffective; Fatigue; Hepatic Cirrhosis; Herpes Zoster; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Arava	S	Unknown	Not Reported
	Celecoxib	S	Unknown	Not Reported
	Celecoxib	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Celebrex	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	13704410	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-1955888			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death;	Actemra			S	Unknown			Not Reported

Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Actemra	S		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Ilaris	S	Intravenous (not otherwise specified)	Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

Sulfasalazine	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S		Not Reported
Arava	S	Unknown	Not Reported
Arava	S		Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Marijuana	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Minocycline	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Oxycodone	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Sodium Aurothiomalate	S		Not Reported
Rituxan	S	Unknown	Not Reported
Rituxan	S		Not Reported
Xeljanz	S	Oral	Not Reported
Kineret	C	Unknown	Not Reported
Lyrica	C	Unknown	Not Reported
Urelumab	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	13932807	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017292		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Adverse Drug Reaction; Arthralgia; Arthropathy; Drug Ineffective; Fatigue; Groin Pain; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling;	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Retinal Toxicity; Rheumatoid Arthritis; Sleep Disorder; Swelling; Swelling	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Tramadol Hydrochloride	C	Oral	50 Mg, Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Xeljanz	C	Oral	50 Mg, Bid	Not Reported
	Rabeprazole Sodium	C	Unknown	20 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	14169090	EXPEDITED (15-DAY)		OT	CA-SA-2017SA210728			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Leflunomide			S	Oral	20 Mg,Unk		Sanofi
	Sodium Aurothiomalate			S	Parenteral	50 Mg,Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg,Unk		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Methotrexate			S	Unknown	20 Mg,Qd		Not Reported
	Actemra			S	Unknown	8 Mg,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	750 Mg,Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	14249112	EXPEDITED (15-DAY)		DS, OT	CA-SA-2017SA232046			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Hydroxychloroquine	S	Oral	200 Mg,Bid		Sanofi
	Arava	S	Oral	20 Mg		Sanofi
	Methotrexate	S	Subcutaneous	20 Mg,Qw		Not Reported
	Methotrexate	S	Subcutaneous	20 Mg		Not Reported
	Prednisone	S	Oral	1 Df, Qd		Not Reported
	Sulfasalazine	S	Unknown	1000 Mg,Bid		Not Reported
	Enbrel	S	Subcutaneous	50 Mg		Not Reported
	Humira	S	Subcutaneous	20 Mg, Qd		Not Reported
	Humira	S	Subcutaneous	Unk Unk, Qd		Not Reported
	Actemra	S	Unknown	Unk Unk,Unk		Not Reported
	Orencia	S	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz	C	Oral	5 Mg,Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	15631632	EXPEDITED (15-DAY)		DE, OT	CA-TEVA-2018-CA-978035		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diffuse Large B-Cell Lymphoma	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Methotrexate Sodium			S	Unknown			Barr
	Methotrexate Sodium			S				Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Mycophenolate Mofetil			S				Teva
	Prednisone			S	Unknown			Actavis
	Prednisone Acetate			S	Unknown	15 Milligram Daily;		Actavis
	Prednisone Acetate			S				Actavis
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Hydroxychloroquine			S				Not Reported
	Rituximab			S	Unknown			Not Reported

	Rituximab	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	15705980	EXPEDITED (15-DAY)		OT	CA-009507513-1812CAN000060			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Off Label Use; Product Use Issue; Rash; Therapeutic Product Effect Decreased	Fosamax			S	Unknown	Unk		Merck
	Vasotec			S	Unknown	Unk		Merck
	Vasotec			S	Unknown	Unk		Merck
	Cozaar			S	Unknown	Unk		Merck
	Cozaar			S	Unknown	Unk		Merck
	Arava			S	Unknown	Unk		Not Reported
	Biaxin			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Clindamycin			S	Unknown	Unk, Unknown		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, 1 Every 1 Week		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, 1 Every 1 Week		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Hydralazine Hydrochloride			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Levaquin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram, 1 Every 1 Week		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram		Not Reported

Methotrexate	S		Unk	Not Reported
Metoprolol Tartrate	S	Unknown	Unk	Not Reported
Moxifloxacin Hydrochloride	S	Unknown	Unk	Not Reported
Pantoprazole Magnesium	S	Unknown	Unk	Not Reported
Pariet	S	Unknown	Unk	Not Reported
Penicillin G	S	Unknown	Unk	Not Reported
Penicillin G	S	Unknown	Unk	Not Reported
Keflex	S	Unknown	Unk, Unknown	Not Reported
Penicillin (Unspecified)	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Cephalexin	S	Unknown	Unk	Not Reported
Cephalexin	S	Unknown	Unk	Not Reported
Diazide (Gliclazide)	S	Unknown	Unk	Not Reported
Isoniazid	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	50 Milligram, 2 Every 1 Day(S)	Not Reported
Lopressor	S	Unknown	Unk	Not Reported
Tecta	S	Unknown	Unk	Not Reported
Cipro (Ciprofloxacin)	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
Iron Sucrose	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	8.5 Milligram, 1 Every 1 Day	Not Reported
Venofer	C	Unknown	Unk	Not Reported
Atenolol	C	Unknown	Unk	Not Reported
Colchicine	C	Unknown	Unk	Not Reported
Coversyl (Perindopril Erbumine)	C	Unknown	Unk	Not Reported

	Leucovorin	C	Unknown	Unk		Not Reported
	Levothyroxine Sodium	C	Unknown	Unk		Not Reported
	Ranitidine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	15871101	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1004862		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Hepatotoxicity; Treatment Failure	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	15881000	EXPEDITED (15-DAY)		HO, OT	GR-MYLANLABS-2019M1007066		56 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Drug Ineffective; Dyspnoea; Leukopenia; Microangiopathic Haemolytic Anaemia; Orthopnoea; Product Use In Unapproved Indication; Raynaud'S Phenomenon; Renal Impairment; Scleroderma Renal Crisis; Scleroedema; Therapy Non-Responder; Thrombocytopenia; Weight Decreased	Alprazolam			S	Unknown	Unk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	10 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	7.5 Milligram, Qd		Not Reported
	Citalopram			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qw		Not Reported
	Captopril			S	Unknown	Unk		Not Reported
	Captopril			S				Not Reported
	Etanercept			S	Unknown	Unk		Mylan
	Etanercept			S				Mylan
	Folic Acid			S	Unknown	5 Milligram, Qw		Mylan
	Folate Sodium			S	Unknown	5 Milligram, Qw		Mylan
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported

Hydroxychloroquine	S	Unknown	Unk		Not Reported
Valsartan	C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	16057413	NON-EXPEDITED			US-PFIZER INC-2019103272		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S				Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Sulfasalazine			S				Pfizer
	Plaquenil			S		Unk		Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	16135292	EXPEDITED (15-DAY)		OT	DE-SA-2018SA251992		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Hydroxychloroquine Sulfate			S	Subcutaneous			Sanofi
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Plaquenil			S	Oral	2 Df, Qd		Sanofi
	Plaquenil			S	Oral	10 Mg, Qd (5mg Bid)		Sanofi
	Plaquenil			S	Oral	10 Mg, Qd		Sanofi
	Plaquenil			S	Oral	Unk		Sanofi
	Plaquenil			S				Sanofi
	Sulfasalazine			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral			Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Methotrexate			S	Oral	20 Mg Tablet		Not Reported

Methotrexate	S	Oral	20 Unk	Not Reported
Methotrexate	S	Subcutaneous	20 Mg	Not Reported
Methotrexate	S	Subcutaneous	20 Mg	Not Reported
Methotrexate Sodium	S		20 Mg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Ciclosporin	S			Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
Humira	S	Subcutaneous	Unk, Solution Subcutaneous	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Neoral	S	Oral		Not Reported
Orencia	S	Subcutaneous	125 Mg	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk, Solution Intravenous	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous		Not Reported
Xeljanz	C	Unknown	2 Df, Qd, 2ot	Not Reported
Xeljanz	C	Oral	10 Mg, Qd (5 Mg, Bid)	Not Reported
Xeljanz	C	Oral	5 Mg, Qd	Not Reported
Xeljanz	C	Oral	10 Mg, Qd	Not Reported
Xeljanz	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	16198298	EXPEDITED (15-DAY)		OT	CA-009507513-1904CAN006267		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Clear Cell Renal Cell Carcinoma; Hair Follicle Tumour Benign; Lymphoproliferative Disorder; Off Label Use; Product Use In Unapproved Indication	Fosamax	S	Unknown	Unk	Merck
	Vasotec	S	Unknown		Merck
	Acetazolamide	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Calcium Carbonate	S	Unknown	Unk	Not Reported
	Cyclosporine	S	Unknown	Unk	Not Reported
	Cyclosporine	S	Unknown	Unk	Not Reported
	Cyclosporine	S	Unknown	Unk	Not Reported
	Cyclosporine	S	Unknown	Unk	Not Reported
	Iron Polymaltose	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Infliximab	S	Unknown	1 Every 1 Month, Qm	Not Reported
	Infliximab	S	Unknown	1 Every 1 Month, Qm	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Cyclophosphamide	S	Unknown		Not Reported
	Ferrous Fumarate	S	Unknown		Not Reported
	Insulin	S	Unknown		Not Reported
	Metformin	S	Unknown		Not Reported
	Nutropin (Atropine Sulfate)	S	Subcutaneous	Formulation Liquid	Not Reported

Protropin	S	Intramuscular	Formulation Liquid	Not Reported
Ranitidine	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	1000 Milligrams, 1 Every 1 Months	Not Reported
Remicade	S			Not Reported
Remicade	S			Not Reported
Sulfamethoxazole	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	1 Dosage Form; Dosage Form Powder For Solution Intravenous	Not Reported
Remicade	S			Not Reported
Amlodipine	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Testosterone	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	16211049	EXPEDITED (15-DAY)		HO, LT, OT	CA-SA-2017SA020214		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthritis; Arthropathy; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Condition Aggravated; Diarrhoea; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension;	Hydroxychloroquine			S	Oral	5 Mg/Kg,Qd		Sanofi
	Hydroxychloroquine			S				Sanofi
	Immunoglobulins (Immunoglobulin Human Normal)			S	Intravenous (not otherwise specified)	70 G,Unk		Not Reported
	Immunoglobulins (Immunoglobulin Human Normal)			S	Intravenous (not otherwise specified)	70 G,Unk		Not Reported
	Immunoglobulins (Immunoglobulin Human Normal)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg/M2,Qow		Not Reported
	Methotrexate			S	Unknown	Unk Unk,Qw		Not Reported
	Naproxen			S	Unknown	Unk Unk,Unk		Not Reported
	Prednisone			S	Oral	5 Mg,Bid		Not Reported

Immunodeficiency; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Short Stature; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Prednisone	S	Oral	3 Mg,Bid	Not Reported
	Prednisone	S	Unknown	1.3 Mg, Bid	Not Reported
	Isoniazid/Rifampicin	S	Intravenous (not otherwise specified)	Unk	Sanofi
	Sulfasalazine	S	Oral	250 Mg,Qd	Not Reported
	Adalimumab	S	Unknown	Unk Unk,Unk	Not Reported
	Abatacept	S	Intravenous (not otherwise specified)	250 Mg,Qm	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Mg,Qow	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qw	Not Reported
	Anakinra	S	Subcutaneous	50 Mg,Qd	Not Reported
	Anakinra	S	Subcutaneous	50 Unk	Not Reported
	Etanercept	S	Subcutaneous	25 Mg,Qw	Not Reported
	Etanercept	S	Subcutaneous	12.5 Mg,Qw	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg/Kg,Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Mg,Unk	Not Reported
	Triamcinolone	S	Unknown	Unk Unk,Unk	Not Reported
	Triamcinolone	S	Unknown	Unk Unk,Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg,Unk	Not Reported
	Enbrel	S	Subcutaneous	25 Mg,Qw	Not Reported
	Tocilizumab	S		250 Mg, Qd	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Qcy (Every 2 Weel)	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Folic Acid	C			Not Reported
	Triamcinolone Hexacetonide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	16226782	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110561			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S		Unk		Sanofi
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Enbrel			S		Therapy Duration: 366.0		Not Reported
	Orencia			S		Therapy Duration: 365.0		Not Reported
	Sulfasalazine			S				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	16646745	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202640			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil			S		2 Df, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	2 Df, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Leflunomide			S	Oral	1 Df, Qd		Sanofi
	Arava			S	Unknown			Sanofi
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported

Orencia	S	Unknown	Unk		Not Reported
Actemra	S		Unk		Not Reported
Azathioprine	S	Unknown	Unk, Unk		Not Reported
Azathioprine	S	Unknown	Unk		Not Reported
Enbrel	S	Subcutaneous	2 Df, Qw		Not Reported
Gold	S	Unknown	Unk		Not Reported
Acetylsalicylic Acid	C	Unknown	81 Mg, Qd		Not Reported
Tiaprofenic Acid	C	Unknown	300 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	16646786	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202522		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Methotrexate			S		20 Mg, Qw		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Advil [Ibuprofen]			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	16648293	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202693		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Gait Inability; Hypogammaglobulinaemia; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate	S	Unknown			Sanofi
	Leflunomide	S	Unknown			Sanofi
	Methotrexate	S	Oral	15 Mg, Qw		Not Reported
	Sulfasalazine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	16652291	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202820			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Soft Tissue Disorder; Synovitis	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Methotrexate			S	Unknown	25 Mg, Qw		Not Reported
	Enbrel			S	Unknown	25 Mg, Biw		Not Reported
	Humira			S	Subcutaneous	200 Mg, Bid		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Mg		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Dexamethasone			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Diphenhydramine			C	Unknown			Not Reported
	Dyclonine Hydrochloride			C	Unknown			Not Reported
	Enablex [Darifenacin Hydrobromide]			C				Not Reported

	Hydromorphone	C	Unknown	Not Reported
	Kadian	C	Unknown	Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Intra-articular	Not Reported
	Lasix [Furosemide]	C	Unknown	Not Reported
	Norflex [Orphenadrine Citrate]	C	Unknown	Not Reported
	Omnaris	C	Unknown	Not Reported
	Oxyneo	C	Unknown	Not Reported
	Pantoprazole Sodium Anhydrous	C	Unknown	Not Reported
	Restasis	C		Not Reported
	Rituxan	C	Intravenous (not otherwise specified)	Not Reported
	Synthroid	C		Not Reported
	Trimethoprim	C	Unknown	Not Reported
	Urispas	C		Not Reported
	Vagifem	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	16655165	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202784			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi
	Bacitracin			S				Not Reported
	Methotrexate			S				Not Reported
	Neomycin Sulfate			S				Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Polymyxin B Sulfate			S				Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Prednisone			C	Intramuscular			Not Reported
	Xeljanz			C	Oral	2 Df, Bid, 5mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	16656988	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202955		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Hydroxychloroquine			S		200 Mg, Qd		Sanofi
	Arava			S		1 Df, Qd		Sanofi
	Methotrexate			S		25 Mg		Not Reported
	Sulfasalazine			S		1500 Mg		Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	16716102	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20190803947			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Blood Cholesterol Increased; Bone Erosion; Bronchitis; Contraindicated Product Administered; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Exostosis; Foot Deformity; Headache; Hepatic Cirrhosis; Hypertension; Infection; Joint Dislocation; Joint Stiffness; Malaise; Nasopharyngitis; Nausea; Off Label Use;	Otezla			S	Oral			Celgene
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Osteoarthritis; Osteoporosis; Pneumonia; Psoriasis; Synovitis; Tachycardia; Upper Respiratory Tract Infection	Rituxan	S	Intravenous drip		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous drip		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sirukumab	S	Unknown		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral	10 Milligram	Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Telmisartan	S	Unknown		Not Reported
	Zopiclone	S	Unknown		Not Reported
	Amlodipine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Cosentyx	S	Unknown		Not Reported
	Amitriptyline	C	Oral		Not Reported
	Betamethasone	C	Topical		Not Reported
	Betamethasone Dipropionate W/Calcipotriol	C	Unknown		Not Reported
	Melatonin	C	Unknown		Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported
	Dilaudid	C	Unknown		Not Reported
	Wellbutrin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	16957606	EXPEDITED (15-DAY)		DE, HO	CA-TEVA-2019-CA-1125473		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congestive Cardiomyopathy;	Methotrexate			S	Unknown	2.5 Milligram Daily; Administered 6 Days A		Barr

Disseminated Varicella Zoster Vaccine Virus Infection; Gastrointestinal Disorder; Leukopenia; Lung Disorder; Multiple Organ Dysfunction Syndrome; Thrombocytopenia	Prednisone	S	Unknown	Week; Ongoing For 3 Years 10 Milligram Daily; Tapered One Month Prior To Presentation		Actavis
	Hydroxychloroquine	S	Unknown	200 Milligram Daily;		Not Reported
	Zostavax Ii	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	16971655	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20191006447			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Colitis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nausea; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting; White Blood Cell Count Decreased	Otezla			S	Oral	60 Milligram		Celgene
	Actemra			S	Unknown			Not Reported
	Cosentyx			S	Unknown	150 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous	125 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Sulfasalazine			C	Unknown	2 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17026290	EXPEDITED (15-DAY)		HO	CA-ROCHE-2459593		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper;	Actemra			S	Unknown			Not Reported

Alopecia; Arthralgia; Bone Pain; Burning Sensation; Choking; Cough; Drug Ineffective; Drug Intolerance; Facial Pain; Fatigue; Fibromyalgia; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Insomnia; Joint Range Of Motion Decreased; Lipoma; Melanocytic Naevus; Nasal Discomfort; Nausea; Night Sweats; Oropharyngeal Discomfort; Osteoporosis; Pain; Pain In Extremity; Pain In Jaw; Peripheral Coldness; Platelet Count Decreased; Rhinorrhoea; Skin Mass	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	Therapy Duration 5.0 Month(S)	Not Reported
	Methotrexate	S	Unknown	Therapy Duration 4.0 Month(S)	Not Reported
	Orencia	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral	Therapy Duration -229.0	Not Reported
	Morphine	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17303675	EXPEDITED (15-DAY)		DE	CA-009507513-2001CAN007751		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Fosamax			S	Unknown	70 Milligram, 1 Every 1 Weeks		Merck
	Flovent			S	Unknown	Dosage Form: Not Specified, Unk		Not Reported
	Albuterol Sulfate (+) Ipratropium Bromide			S	Unknown	Dosage Form: Solution Inhalation, Unk		Not Reported
	Lasix (Furosemide Sodium)			S	Unknown	40 Milligram, Unk; Dosage Form: Not Specified		Not Reported
	Lipitor			S	Unknown	10 Milligram, Unk; Dosage Form: Not Specified		Not Reported
	Losec (Omeprazole Magnesium)			S	Oral	20 Milligram, Unk; Dosage Form: Not Specified		Not Reported

	Metformin	S	Unknown	500 Milligram, 2 Every 1 Days	Not Reported
	Nitrazadon	S	Unknown	10 Milligram, Unk	Not Reported
	Plaquenil	S	Unknown	300 Milligram, 1 Every 1 Days	Not Reported
	Prednisone	S	Unknown	5 Milligram,1 Every 1 Days, Dosage Form: Not Specified	Not Reported
	Salmeterol Xinafoate	S	Unknown	Unk	Not Reported
	Tylenol	S	Unknown	500 Milligram, Unk; Dosage Form: Not Specified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17518925	EXPEDITED (15-DAY)		OT	CA-ROCHE-2564559		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Parenteral			Not Reported

	Orencia	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Tofacitinib	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17570987	NON-EXPEDITED			US-PFIZER INC-2020121578		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, 0, 2, 6 Wks, Then Every 8 Wks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 8 Weeks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 7 Weeks		Not Reported
	Humira			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Otrexup			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17663764	EXPEDITED (15-DAY)		OT	US-ROCHE-2580025			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Abnormal Dreams; Alopecia; Anaemia; Cytopenia; Depressed Mood; Dizziness; Dry Mouth; Fatigue; Gastrointestinal Disorder; Hirsutism; Infection; Insomnia; Leukopenia; Palpitations; Transaminases Increased	Mycophenolate Mofetil	S	Unknown	Not Reported
	Mycophenolic Acid	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Methylprednisolone	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Doxycycline	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17678874	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202004002607			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Bronchopulmonary Aspergillosis; Catheter Bacteraemia; Off Label Use; Pneumomediastinum; Pneumonia Bacterial; Pneumonia Bacterial; Renal Failure; Shock Haemorrhagic	Hydroxychloroquine			S		400 Mg, Qd (Film-Coated Tablet)		Concordia
	Heparine			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17726960	EXPEDITED (15-DAY)		HO, OT	FR-ADVANZ PHARMA-202004004250			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Chondrocalcinosis; Off Label Use; Systemic Inflammatory Response Syndrome	Hydroxychloroquine			S	Oral	400 Mg, Qd, Film-Coated Tablet		Concordia
	Hydroxychloroquine			S		400 Mg, Qd, Film-Coated Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17727561	EXPEDITED (15-DAY)		LT	FR-MYLANLABS-2020M1042619		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Ventricular Tachycardia	Azithromycin			S	Oral	250 Milligram, Qd		Not Reported
	Lasilix /00032601/			S	Intravenous (not otherwise specified)	2 Dosage Form, Qd		Mylan
	Plaquenil /00072603/			S	Oral	Unk		Mylan
	Sufentanil			C	Intravenous (not otherwise specified)	Unk		Mylan
	Perfalgan			C	Intravenous (not otherwise specified)	Unk		Mylan
	Noradrenaline /00127501/			C	Intravenous (not otherwise specified)	Unk		Mylan
	Midazolam			C	Intravenous (not otherwise specified)	Unk		Mylan
	Tazocilline			C	Intravenous (not otherwise specified)	4 Dosage Form, Qd		Mylan
	Transipeglib			C	Oral	Unk		Mylan
	Potassium Chloride			C	Intravenous (not otherwise specified)	Unk		Mylan
	Nimbex /01302502/			C	Intravenous (not otherwise specified)	Unk		Mylan
	Ultibro Breezhaler			C	Respiratory (inhalation)	Unk		Mylan
	Seresta			C	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17736227	EXPEDITED (15-DAY)		DE	ES-MYLANLABS-2020M1043094		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Sudden	Levofloxacin			S	Unknown	Unk		Not Reported

Death	Azithromycin	S	Oral	500 Milligram, Qd	Not Reported
	Lopinavir/Ritonavir	S	Oral	2 Dosage Form, Bid	Not Reported
	Tacrolimus	S		Unk	Mylan
	Hidroxicloroquina Sulfato	S	Oral	200 Milligram, Qd	Mylan
	Ceftriaxona /00672201/	C	Unknown	Unk	Mylan
	Enoxaparina Sodica	C	Subcutaneous	40 Milligram, Qd	Mylan
	Prednisona	C	Oral	20 Milligram, Qd	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17744110	EXPEDITED (15-DAY)		LT, OT	FR-MYLANLABS-2020M1043359		18 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Diabetic Metabolic Decompensation; Haemoglobin Decreased; Hepatocellular Injury; Inflammation; Pyrexia; Respiratory Disorder	Midazolam			S	Intravenous (not otherwise specified)	5 Mg/Ml, Qd		Not Reported
	Lovenox			S	Subcutaneous	0.6 Ml, Qd		Mylan
	Hydroxychloroquine Sulfate			S	Unknown	1200 Milligram, Qd		Mylan
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Mylan
	Omeprazole			S	Intravenous (not otherwise specified)	20 Milligram, Qd		Mylan
	Omeprazole			S	Intravenous (not otherwise specified)	40 Milligram, Qd		Mylan
	Loxen /00890702/			S	Intravenous (not otherwise specified)	30 Milligram, Qd		Mylan
	Movicol /01749801/			S	Other	2 Df Bag		Mylan
	Novorapid			C	Intravenous (not otherwise specified)	Unk		Mylan
	Omeprazol 1 A Pharma			C	Other	20 Mg, Qd		Mylan
	Paracetamol			C	Other	4 G, Qd		Mylan
	Paracetamol			C				Mylan
	Diffu K			C	Unknown	3.6 Gram, Qd		Mylan
	Lasilix /00032601/			C		30 Milligram, Qd		Mylan

	Doliprane	C	Unk			Mylan
	Doliprane	C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17760562	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2020183153			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Pneumonitis; Psoriasis; Urticaria	Infliximab			S	Unknown	Unk		Unknown
	Levofloxacin			S		Unk		Pfizer
	Methylprednisolone Acetate			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17766483	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020185574		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis Acute; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Single		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17782613	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593919		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity;	Actemra			S	Unknown			Not Reported

Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Rituximab	S	Intravenous drip	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Mycophenolate Mofetil	S		Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Lyrica	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Piroxicam	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17787717	EXPEDITED (15-DAY)		DE	MX-ADVANZ PHARMA-202004005019			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemodynamic Instability; Off Label Use	Hydroxychloroquine			S		200 Mg, Bid (Q12h)		Concordia
	Hydroxychloroquine			S				Concordia
	Furosemide			C				Not Reported
	Clarithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Enoxaparin			C				Not Reported
	Methylprednisolone			C				Not Reported
	Meropenem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17787749	EXPEDITED (15-DAY)		DS, HO, OT	CA-SAMSUNG		54 YR	Female	CAN

BIOEPIS-SB-2020-15795

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Disorder; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation	Infliximab			S	Oral	Unknown		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown	Unknown		Not Reported
	Apo-Ibuprofen			S	Oral	Unknown		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apremilast			S	Unknown	Unknown		Not Reported
	Apremilast			S	Unknown			Not Reported
	Apremilast			S				Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Cyclosporin			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Tongue Disorder; Ulcer	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Ibuprofen	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Motrin [Ibuprofen]	S	Oral		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Myochrysine	S	Intramuscular		Not Reported

Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Subcutaneous	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituxan	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous	Unknown	Not Reported
Stelara	S	Subcutaneous	Unknown	Not Reported
Sulfasalazine	S	Endocervical		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Codeine	S	Unknown	Unknown	Not Reported
Otezla	S	Unknown	Unknown	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unknown	Not Reported
Colchicine	C	Oral	Unknown	Not Reported
Dexilant	C	Oral	Unknown	Not Reported
Febuxostat	C	Unknown	Unknown	Not Reported
Folic Acid	C	Unknown	Unknown	Not Reported
Gravol	C	Unknown	Unknown	Not Reported
Mogadon	C	Oral		Not Reported
Nitrazepam	C	Unknown		Not Reported
Oxycodone	C	Unknown	Unknown	Not Reported
Prednisolone	C	Unknown		Not Reported
Prednisolone	C	Unknown		Not Reported

	Prednisone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Uloric	C	Unknown		Not Reported
	Xeljanz	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17788081	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-024673		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Quetiapine Arrow Lp 50 Mg Prolonged Release Tablet			S	Oral	100 Milligram, Once A Day		Aurobindo
	Zithromax			S	Oral	250 Milligram, Once A Day		Not Reported
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17788113	EXPEDITED (15-DAY)		HO	ES-ACCORD-181994		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Azithromycin			S	Oral	500 Mg Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17788220	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2598905		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Rituximab	S		Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Ilaris	S	Unknown	Not Reported
	Ilaris	S	Intravenous (not otherwise specified)	Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17788293	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597595		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Synovitis	Tocilizumab			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17788419	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596424		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17788436	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020192176		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fall; Gait Inability; Malaise; Paralysis; Spinal Fracture	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17788502	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234906		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Pain; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Acetaminophen			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Barr
	Methotrexate			S	Subcutaneous	25 Milligram		Barr
	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown	7.5 Milligram		Actavis
	Actemra			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17789376	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247219		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Hepatitis	Azithromycin	S	Oral	500 Milligram, Daily		Sun
	Hidroxicloroquina (2143a)	S	Oral	400 Milligram, Daily		Not Reported
	Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	2 Gram, Daily		Not Reported
	Tocilizumab (8289a)	S	Intravenous (not otherwise specified)	600 Mg ; In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17790293	EXPEDITED (15-DAY)		HO, OT	FR-IPCA LABORATORIES LIMITED-IPC-2020-FR-001539			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Dysphagia; Musculoskeletal Toxicity; Myopathy Toxic; Toxicity To Various Agents; Weight Decreased	Chloroquine			S	Unknown	200 Milligram, Qd		Ipca
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Ipca
	Acetylsalicylic Acid			C	Unknown	75 Milligram, Qd		Not Reported
	Clopidogrel			C	Unknown	75 Milligram, Qd		Not Reported
	Fenofibrate			C	Unknown	100 Milligram, Qd		Not Reported
	Ranitidine			C	Unknown	300 Milligram, Qd		Not Reported
	Clobetascol			C	Unknown	Unk, Qd		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Tramadol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17790373	EXPEDITED (15-DAY)		OT	NVSC2020KR130316		59 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Optic Neuritis; Retinopathy	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Novartis
	Methylprednisolone			S	Intravenous (not otherwise specified)	1 G, Qd		Not Reported
	Prednisolone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17790411	EXPEDITED (15-DAY)		OT	NVSC2020IT130474		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Pyrexia; Systemic Lupus Erythematosus	Mycophenolate Mofetil			S	Unknown	Unk Unk, Qd		Novartis
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk Unk (7.5 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S	Unknown	Unk (50 Mg Qd, Tapering Dose)		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk Unk (15 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S	Unknown	Unk (25 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S	Unknown	Unk Unk (10 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S	Unknown	Unk Unk (12.5 Mg Qd, Dose Tapering)		Not Reported
	Tacrolimus			S	Unknown	Unk Unk, Qd		Not Reported
	Methylprednisolone			C		Unk (Pulses)		Not Reported
	Rituximab			C	Unknown	Unk		Not Reported
	Immunoglobulin I.V			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17791337	EXPEDITED (15-DAY)		HO, OT	FR-SA-2020SA125110		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Off Label Use; Ventricular Fibrillation	Plaquenil			S	Oral			Sanofi
	Plaquenil			S				Sanofi

	Lasilix	S	Oral	Unk		Sanofi
	Risordan	S	Intravenous (not otherwise specified)			Not Reported
	Irbesartan	S	Oral	Unk		Sanofi
	Carvedilol	S	Oral	Unk		Not Reported
	Azithromycin	S	Oral	250 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17791355	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-001382			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrasystoles; Palpitations	Hydroxychloroquine			S	Unknown	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17791635	EXPEDITED (15-DAY)		OT	ES-ACCORD-182005		83 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg Dia		Not Reported
	Azithromycin			S	Oral	500 Mg Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17791638	EXPEDITED (15-DAY)		OT	GB-ACCORD-181984		48 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrasystoles; Palpitations	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17791654	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234484		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling	Prednisone	S	Unknown			Actavis
	Prednisone	S				Actavis
	Methotrexate	S	Subcutaneous			Barr
	Methotrexate	S				Barr
	Arava	S	Oral			Not Reported
	Arava	S				Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Hydroxychloroquine Sulfate	S				Not Reported
	Infliximab	S	Unknown			Not Reported
	Infliximab	S				Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown	1000 Milligram Daily;		Not Reported
	Sulfasalazine	S				Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz	S				Not Reported
	Atorvastatin	C	Unknown			Not Reported
	Pantoloc [Pantoprazole]	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17791682	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1046807		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hyponatraemia	Levofloxacin			S	Oral	500 Mg Dia		Not Reported
	Dolquine			S	Oral	400 Mg Dia		Mylan
	Kaletra			S	Oral	2u / 12 H		Mylan
	Kaletra			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17791698	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1234911		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Amnesia; Cardiovascular Disorder; Condition Aggravated; Cystitis; Deformity; Depressed Mood; Dermatitis; Drug Ineffective; Encephalitis; Encephalitis Brain Stem; Fall; Fibromyalgia; Immobile; Immune System Disorder; Immunodeficiency; Joint Destruction; Loss Of Personal Independence In Daily Activities; Memory Impairment; Pain; Peripheral Swelling; Psychiatric Symptom; Rheumatoid Arthritis; Rib Fracture; Scar; Seizure; Sepsis; Spinal Deformity; Vomiting	Methotrexate	S	Unknown			Barr
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Arava	S	Unknown			Not Reported
	Celebrex	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Lyrica	C	Oral			Not Reported
	Prednisone	C	Unknown	14 Milligram Daily;		Not Reported
	Dilaudid	C	Unknown	12 Milligram Daily;		Not Reported
	Furosemide	C	Unknown			Not Reported
	Hydromorph Contin	C	Unknown	54 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17791711	EXPEDITED (15-DAY)		OT	ES-ACCORD-181713		51 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg / 12h From 14-Apr-2020 To 17-Apr-2020		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2gr/24h		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg / 24 H From 11-Apr-2020 To 12-Apr-2020, 400 Mg / 12 H From 14-Apr-2020 To 17-Apr-2020		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17791732	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595998		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Off Label Use	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Desoximetasone			C	Oral			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C	Subcutaneous			Not Reported
	Zostavax			C	Subcutaneous	Powder For Suspension Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17791733	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597016		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported

	Caffeine	C	Not Reported
	Arava	C	Not Reported
	Folic Acid	C	Not Reported
	Leflunomide	C	Not Reported
	Methotrexate	C	Not Reported
	Naproxen	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17791743	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-15914			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Disorder; Bronchiectasis; Bursitis; Bursitis Infective; Crying; Erythema; Gastrointestinal Disorder; Infection; Joint Range Of Motion Decreased; Localised Infection; Osteoporosis; Peripheral Vascular Disorder; Photosensitivity Reaction; Pneumonia; Renal Failure; Respiratory Tract Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Swelling; Synovitis; Tenosynovitis; Therapeutic Product Effect Incomplete	Infliximab			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Acetaminophen			C	Unknown	Unknown		Not Reported
	Acidophilus			C	Unknown	Unknown		Not Reported
	Aspirin			C	Unknown	Unknown		Not Reported
	Calcium			C	Unknown	Unknown		Not Reported
	Deflazacort			C	Unknown	Unknown		Not Reported
	Dilaudid			C	Unknown	Unknown		Not Reported
	Ergocalciferol			C	Unknown	Unknown		Not Reported
	Hydromorphone Hydrochloride			C	Unknown	Unknown		Not Reported
	Januvia			C	Unknown	Unknown		Not Reported

Kenalog	C	Unknown	Unknown		Not Reported
Lidocaine	C	Topical	Unknown		Not Reported
Metronidazole	C	Unknown	Unknown		Not Reported
Nitroglycerin	C	Unknown	Unknown		Not Reported
Pantoloc	C	Unknown	Unknown		Not Reported
Pregabalin	C	Unknown	Unknown		Not Reported
Risedronate	C	Unknown	Unknown		Not Reported
Rosuvastatin Calcium	C	Unknown	Unknown		Not Reported
Salbutamol	C	Unknown	Unknown		Not Reported
Triamcinolone	C	Unknown	Unknown		Not Reported
Xeljanz	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17791808	DIRECT	Y	LT			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine Sulfate			S	Oral			Sandoz
	Acetaminophen 650 Mg Po			C				Not Reported
	Maalox-Plus 30 Ml Po			C				Not Reported
	Albuterol Mdi			C				Not Reported
	Enoxaparin 40mg Sc			C				Not Reported
	Levofloxacin 750mg Po			C				Not Reported
	Melatonin 3mg			C				Not Reported
	Ondansetron 4mg Ivp			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17792081	EXPEDITED (15-DAY)		DE, HO, OT	US-ADVANZ PHARMA-202004005069			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epstein-Barr Virus Infection Reactivation; Klebsiella Infection; Off Label Use; Pneumonia	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Concordia
	Hydroxychloroquine			S				Concordia
	Cyclophosphamide			S	Unknown	14.5 Mg/Kg Days -6 And -		Not Reported

Adenoviral; Pneumonia Escherichia				5		
	Cyclophosphamide	S	Unknown	500 Mg/Kg Days 3 And 4		Not Reported
	Fludarabine Phosphate	S	Unknown	30 Mg/M2 From Days -6 Through -2		Not Reported
	Prednisone	S	Unknown	15 Mg, Qd		Not Reported
	Prednisone	S				Not Reported
	Mesalazine	S	Unknown	1.2 G, Bid Q12h		Not Reported
	Mesalazine	S				Not Reported
	Azathioprine	S	Unknown	150 Mg, Qd		Not Reported
	Azathioprine	S				Not Reported
	Busulfan	S	Intravenous (not otherwise specified)	Unk, Qd On Days -4, -3,-2		Not Reported
	Sirolimus	S	Unknown	Unk		Not Reported
	Basiliximab	S	Unknown	Unk		Not Reported
	Infliximab	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17792157	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1234794		59 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 G, Day		Not Reported
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17792348	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2020192350		96 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arrhythmia; Extrasystoles; Off Label Use; Product Use In Unapproved Indication	Azithromycin	S	500 Mg, 1x/Day	Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]	S	400 Mg, 1x/Day	Not Reported
	Novorapid	C		Not Reported
	Movicol [Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Ch	C		Not Reported
	Cardirene	C	75 Mg	Not Reported
	Pantorc	C	20 Mg	Not Reported
	Lantus	C		Not Reported
	Metoprololo	C	50 Mg	Not Reported
	Dobetin [Cyanocobalamin]	C		Not Reported
	Normix	C		Not Reported
	Lasix [Furosemide]	C		Not Reported
	Deltacortene	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17792351	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235702			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported

Reactine (Cetirizine)	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17792361	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235646			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17792436	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234988			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Disorder; Bronchiectasis; Bursitis; Bursitis Infective; Crying; Erythema; Gastrointestinal Disorder; Infection; Joint Range Of Motion	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown	20 Milligram Daily;		Not Reported

Decreased; Localised Infection; Osteoporosis; Peripheral Vascular Disorder; Photosensitivity Reaction; Pneumonia; Renal Failure; Respiratory Tract Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Swelling; Synovitis; Tenosynovitis; Therapeutic Product Effect Incomplete	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Infliximab	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Acidophilus	C	Unknown	Not Reported
	Aspirin [Acetylsalicylic Acid]	C	Unknown	Not Reported
	Calcium	C	Unknown	Not Reported
	Deflazacort	C	Unknown	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Hydromorphone Hydrochloride	C	Unknown	Not Reported
	Januvia	C	Unknown	Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Unknown	Not Reported
	Metronidazole	C	Unknown	Not Reported
	Nitroglycerin	C	Unknown	Not Reported
	Pantoloc [Pantoprazole]	C	Unknown	Not Reported
	Pregabalin	C	Unknown	Not Reported
	Risedronate	C	Unknown	Not Reported
	Rosuvastatin Calcium	C	Unknown	Not Reported
	Salbutamol	C	Unknown	Not Reported
	Triamcinolone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17792459	EXPEDITED (15-DAY)		LT, OT	JP-HQ SPECIALTY-JP-2020INT000054		38 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Atrioventricular Block First Degree; Covid-19 Pneumonia; Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication; Ventricular Fibrillation; Viral Myocarditis	Dexmedetomidine Hydrochloride			S	Unknown	Unk		Hq Specialty
	Azithromycin			S	Unknown	500 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Favipiravir			C	Unknown	Unk		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Ciclesonide			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	1 Mg/Kg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17792537	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20171028710		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Incorrect Route Of Product Administration; Infection; Pneumonia; Synovitis	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Intra-arterial			Not Reported
	Methotrexate Sodium			S	Intra-articular			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17792663	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1233509		35 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva
	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported
	Rapamune			C	Oral	1 Mg		Not Reported
	Rapamune			C				Not Reported
	Enoxaparina (2482a)			C	Subcutaneous	40 Mg Day		Not Reported
	Deflazacort (2546a)			C	Oral	6 Mg		Not Reported
	Deflazacort (2546a)			C				Not Reported
	Deflazacort (2546a)			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17792744	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2020191417		56 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hypoacusis	Azithromycin			S	Oral	500 Mg, Daily		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17792762	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2020191421		49 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis; Off Label Use; Product Use In Unapproved Indication; Product Use Issue	Azithromycin			S	Oral	500 Mg, Daily		Pfizer
	Azithromycin			S				Pfizer
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, Daily		Not Reported
	Ceftriaxone			S				Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17792773	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2020191268		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Off Label Use; Product Use In Unapproved Indication; Purpura; Thrombocytopenia	Azithromycin			S	Oral	Unk		Pfizer
	Noradrenaline Hospira			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Cefotaxime			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Inexium [Esomeprazole Magnesium]			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			S	Subcutaneous	Unk		Not Reported
	Loxen [Nicardipine Hydrochloride]			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Sufentanil			C		Unk		Not Reported
	Nimbex [Cisatracurium Besilate]			C		Unk		Not Reported
	Hypnovel [Midazolam Hydrochloride]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17793014	EXPEDITED (15-DAY)		OT	CA-SA-2020SA123123			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Fatigue; Joint Swelling; Leukopenia; Nausea; Pain In Extremity; Peripheral Swelling; Vomiting; Weight Decreased	Arava			S	Unknown	1 Every 1 Day		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	1 Every 1 Day		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	2 Every 1 Day		Sanofi
	Methotrexate			S	Unknown	1 Every 1 Week		Not Reported
	Adalimumab			S	Subcutaneous	1 Df		Not Reported
	Calcium			C				Not Reported
	Fentanyl			C				Not Reported

	Folic Acid	C	Not Reported
	Magnesium	C	Not Reported
	Naproxen Sodium	C	Not Reported
	Pantoprazole	C	Not Reported
	Potassium	C	Not Reported
	Tramadol	C	Not Reported
	Vitamin D [Colecalciferol]	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17793016	EXPEDITED (15-DAY)		OT	CA-SA-2020SA123056			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Interstitial Lung Disease; Vomiting	Leflunomide			S	Oral	10 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Sanofi
	Azathioprine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17793017	EXPEDITED (15-DAY)		OT	CA-SA-2020SA123029			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	40 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not	1 G		Not Reported

			otherwise specified)			
	Simponi	S	Subcutaneous			Not Reported
	Tocilizumab	S	Unknown			Not Reported
	Tofacitinib	S	Unknown			Not Reported
	Xeljanz	S	Unknown			Not Reported
	Rabeprazole Sodium	C	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17793233	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234720		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Prednisone			S	Oral			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17793424	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234471			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy;	Methotrexate			S	Intra-arterial	25 Milligram Daily;		Barr

Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Prednisone	S	Unknown			Actavis
	Actemra	S	Unknown			Not Reported
	Arava	S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous			Not Reported
	Desoximetasone	S	Oral			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Folic Acid	S	Unknown			Not Reported
	Fosamax	S	Oral			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole	S	Unknown			Not Reported
	Reactine (Cetirizine)	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown	2 Gram Daily;		Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17793971	EXPEDITED (15-DAY)		HO	CA-ROCHE-2598160			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Etanercept	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17793974	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234505		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Confusional State; Hepatic Steatosis; Infection; Memory Impairment; Nausea; Nightmare; Pain; Polymyalgia Rheumatica; Visual Impairment	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Acetaminophen			C				Not Reported
	Macrobid [Clarithromycin]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794208	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2020M1047539			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Electrocardiogram Qt Prolonged; Intentional Product Misuse; Off Label Use	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	600 Mg, Qd		Mylan
	Oxygen			C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794230	EXPEDITED (15-DAY)		CA	DE-MYLANLABS-2020M1047544			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Talipes	Prednisolone			S	Transplacental	Unk		Not Reported
	Certolizumab			S	Transplacental	Unk		Mylan
	Hydroxychloroquine			S	Transplacental	Unk		Mylan
	Sulfasalazine			S	Transplacental	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794256	EXPEDITED (15-DAY)		HO, LT	ES-MYLANLABS-2020M1047894		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia; Pancreatitis Acute	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Metilprednisolona /00049601/			S	Intravenous (not otherwise specified)	250 Milligram, Qd		Mylan
	Kaletra			S	Oral	2 Dosage Form, Bid		Mylan
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	1 Gram, Qd		Mylan
	Tocilizumab			S	Intravenous (not otherwise specified)	560 Milligram, Qd		Mylan
	Dolquine			S	Oral	200 Milligram, Bid		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794348	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2020M1047857		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Azithromycin			S				Not Reported
	Hidroxicloroquina /00072601/			S	Oral	400 Mg Dia		Mylan
	Hidroxicloroquina /00072601/			S				Mylan
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	2 Gram, Qd 2 Gr Dia		Mylan
	Ceftriaxona /00672201/			S				Mylan

	Tocilizumab	S	Intravenous (not otherwise specified)	600 Mg		Mylan
	Tocilizumab	S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794351	EXPEDITED (15-DAY)		OT	BE-MYLANLABS-2020M1047666		83 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Intentional Product Misuse; Off Label Use	Trazodone			S	Oral	1 Dosage Form, Qd (1 Df, Qd , 1/4 Tablet In The Morning And At Noon And 1/2 Tablet In The)		Not Reported
	Olanzapine			S	Oral	1 Dosage Form, Qd (1 Df Qd, 1/2 Tablet 2x/Day, Treatment Was Suspended For 2 Days 11/04 And 12/04)		Mylan
	Plaquenil /00072603/			S	Oral	Unk (Day 1: 400mg 2x/D; Day 2-4: 200mg 1x/D 7/04 : Received 2x 400 Mg; 08/04 To 10/04)		Mylan
	Clexane			C		Unk		Mylan
	Perindopril			C		1 Dosage Form, Qd (1 Df, Qd)		Mylan
	Movicol /01749801/			C		1 Dosage Form, Qd (1 Df, Qd)		Mylan
	L-Thyroxine /00068001/			C		1 Dosage Form, Qd (1 Df, Qd)		Mylan
	Metformin			C		2 Dosage Form, Qd (2 Df, Qd)		Mylan
	Prolopa			C		0.5 Dosage Form, Qd (0.5 Df, Qd)		Mylan
	Contramal			C		1 Dosage Form, Prn (As Necessary)		Mylan
	Kalium /00031401/			C	Oral	Unk		Mylan

	Algostase Mono	C		3 Dosage Form, Qd (3 Df, Qd)	Mylan
	Pradaxa	C		Unk	Mylan
	Uni Diamicron	C		60 Milligram, Bid (60 Mg, Bid)	Mylan
	Magnetop /00434501/	C	Oral	450 Milligram, Qd (450 Mg, Qd)	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794561	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235275			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diarrhoea; Drug Ineffective; Fibromyalgia; Gastrooesophageal Reflux Disease; Pain; Skin Irritation; Weight Increased	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Ibuprofen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794844	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234509			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diarrhoea; Drug Ineffective; Fibromyalgia; Gastrooesophageal Reflux Disease; Ill-Defined Disorder; Pain; Skin Irritation; Weight Increased	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Ibuprofen			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794857	EXPEDITED (15-DAY)		HO	ES-BAUSCH-BL-2020-014019		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage; Vessel Puncture Site Haemorrhage	Dexametasona			S	Intravenous (not otherwise specified)	20 Mg Dia		Bausch And Lomb
	Enoxaparina			S	Subcutaneous			Not Reported
	Hidroxicloroquina			S	Oral			Not Reported
	Acetylsalicylate Lysine			S	Intravenous (not otherwise specified)	200 Mg, One Total		Not Reported
	Adiro			S	Oral	500 Tablets,1 Cp Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794860	EXPEDITED (15-DAY)		OT	US-SA-2020SA122902		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Lupus Nephritis; Off Label Use; Proteinuria; Treatment Noncompliance	Hydroxychloroquine			S				Sanofi
	Prednisone			S				Not Reported
	Lovenox			S				Sanofi
	Sulfamethoxazole/Trimethoprim			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Azathioprine			S				Not Reported
	Tacrolimus			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794868	EXPEDITED (15-DAY)		OT	CA-SA-2020SA123326		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease	Arava			S		Unk		Sanofi
	Methotrexate			S	Intravenous (not otherwise specified)	Unk		Not Reported

Hydroxychloroquine Sulfate	S		Unk		Sanofi
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Actemra	S		Unk		Not Reported
Acetylsalicylic Acid	C		Unk		Not Reported
Insulin	C		Unk		Not Reported
Lantus	C	Subcutaneous	Unk		Not Reported
Lozide [Gliclazide]	C		Unk		Not Reported
Metformin	C		Unk		Not Reported
Naproxen	C		Unk		Not Reported
Prednisone	C		Unk		Not Reported
Ramipril	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794871	EXPEDITED (15-DAY)		OT	CA-SA-2020SA122626		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Hydroxychloroquine Sulfate			S				Sanofi
	Methotrexate			S				Not Reported
	Leflunomide			S				Sanofi
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S				Not Reported
	Remicade			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794873	EXPEDITED (15-DAY)		OT	CA-SA-2020SA123060			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Leflunomide		S	Oral	Unk	Sanofi
	Hydroxychloroquine Sulfate		S	Oral	400 Mg, Qd (1 Every 1 Day)	Sanofi
	Methotrexate		S	Unknown	25 Mg, Qw (1 Every 1 Week)	Not Reported
	Sulfasalazine		S	Unknown	1 G, Bid (2 Every 1 Day)	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Rituximab		S	Intravenous drip	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794883	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA123045		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Ineffective; Fatigue; Loose Body In Joint; Off Label Use; Osteoporotic Fracture; Pain; Synovitis	Leflunomide			S	Unknown	2 Df, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi
	Naproxen			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794893	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234722		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Diverticulitis; Drug Ineffective; Skin Atrophy; Skin Laceration; Wound	Prednisone			S	Unknown	2.5 Milligram Daily;		Actavis
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Rituximab/Vorhyaluronidase Alfa	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Acetaminophen	C	Oral		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Arava	C	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	C	Unknown		Not Reported
	Enbrel	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Folic Acid	C			Not Reported
	Humira	C	Unknown		Not Reported
	Indapamide	C	Oral	1.25 Milligram Daily;	Not Reported
	Naproxen	C	Unknown		Not Reported
	Orencia	C	Intravenous (not otherwise specified)		Not Reported
	Pantoloc [Pantoprazole]	C	Oral	40 Milligram Daily;	Not Reported
	Perindopril	C	Unknown	2 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794900	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234926		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Cough; Disease Progression; Drug Ineffective; Gait Disturbance; Immobile; Malaise	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown	40 Milligram Daily;		Not Reported
	Celebrex			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17795162	EXPEDITED (15-DAY)		DE, OT	ES-BAUSCH-BL-2020-014022		62 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Hypocoagulable State; Hypofibrinogenaemia; Thrombocytopenia	Dexametasona			S	Intravenous (not otherwise specified)			Bausch And Lomb
	Dexametasona			S	Intravenous (not otherwise specified)	Dose Reduced		Bausch And Lomb
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg In Total		Not Reported
	Hidroxicloroquina			S	Oral			Not Reported
	Azitromicina			S	Oral			Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)			Not Reported
	Enoxaparina			S	Subcutaneous			Not Reported
	Enoxaparina			S	Subcutaneous	Dose Reduced		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17795175	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020195127		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis Acute; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Single		Not Reported
	Tocilizumab			S				Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17795257	EXPEDITED (15-DAY)		HO, LT, OT	JP-INSUD PHARMA-2004JP00069			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adrenal Disorder; Hormone Level Abnormal; Hypogonadism; Infarction; Maternal Exposure During Pregnancy; Off Label Use; Pelvic Infection; Placenta Accreta; Pre-Eclampsia; Proteinuria; Vaginal Haemorrhage	Progesterone	S	Vaginal	300 Mg		Xiromed
	Estrasorb	S	Transdermal			Exceltis Usa
	Tacrolimus Monohydrate	S	Unknown	4 Mg		Not Reported
	Dydrogesterone	S	Oral	15 Milligram Daily		Not Reported
	Prednisolone	S	Unknown	7.5 Mg		Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17797261	DIRECT	Y	LT			85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine Sulfate			S	Oral	Other Frequency:Bid X 1day,Then Qd;		Sandoz
	Acetaminophen 325 Mg			C				Not Reported
	Azithromycin 250 Mg			C				Not Reported
	Baclofen 20mg			C				Not Reported
	Doxazocin 6mg			C				Not Reported
	Famotidine 40mg			C				Not Reported
	Finasteride 5mg			C				Not Reported
	Furosemide 40mg			C				Not Reported
	Milk Of Magnesia 30ml			C				Not Reported
	Rivaroxaban 20mg			C				Not Reported
	Senna Tab 17.2mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17797621	DIRECT	Y				62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17797861	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S				Not Reported
	Quetiapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17797867	DIRECT	Y				86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Coronary Syndrome; Cerebrovascular Accident; Electrocardiogram Abnormal; Electrocardiogram Qt Prolonged; Respiratory Failure; Troponin Increased	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17797872	DIRECT	Y				84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Haemoglobin Decreased	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17797909	DIRECT	Y				82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S				Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	10614679	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1496772		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cardiovascular Disorder; Condition Aggravated; Cystitis; Deformity; Depressed Mood; Dermatitis; Drug Ineffective; Encephalitis; Encephalitis Brain Stem; Fall; Fibromyalgia; Immobile; Immune System Disorder; Immunodeficiency; Insomnia; Joint Destruction; Loss Of Personal Independence In Daily Activities; Memory Impairment; Pain; Peripheral Swelling; Psychiatric Symptom; Rheumatoid Arthritis; Rheumatoid Arthritis; Rib Fracture; Scar; Seizure; Sepsis; Spinal Deformity; Vomiting	Actemra			S	Intravenous (not otherwise specified)	Started Summer 2013, Had 3 Doses In Total		Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown	2009 Or 2012 Start, Stopped Fall 2014. Later Re-Started It Again.		Not Reported
	Celebrex			S	Unknown	Re-Started When Had A Rheumatoid Arthritis Flare		Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	6 Months		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Stopped As Did Not Do Anything		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Dilaudid			C	Unknown	As Needed, Started 2009 Approximately		Not Reported
	Dilaudid			C	Unknown	As Required		Not Reported
	Lyrica			C	Oral	2 Capsules Morning, 1 At Night, 2010 Start Approx.		Not Reported
	Hydromorph Contin			C	Unknown			Not Reported
	Hydromorph Contin			C	Unknown	Sustained Release		Not Reported
	Furosemide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	15377600	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184324		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gastric Disorder; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Off Label Use; Rash; Syncope; Urticaria	Actemra			S	Unknown	Therapy Duration: 365.0		Not Reported
	Actemra			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 366.0		Not Reported
	Rituxan			S				Not Reported
	Arava			S	Oral	Therapy Duration: 365.0		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 3 Months		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 366.0		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 16.0 Years		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 638.0		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Therapy Duration: 8.0 Years		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Therapy Duration: 396.0		Not Reported
	Prednisone			C	Unknown			Not Reported
	Prevacid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17019442	EXPEDITED (15-DAY)		OT	CA-ROCHE-2457981		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Bronchitis; C-Reactive Protein	Actemra			S	Endocervical			Not Reported

Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gait Inability; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Off Label Use; Pain In Extremity; Pneumonia; Skin Reaction; Synovitis; Therapeutic Product Effect Decreased; Thyroid Disorder; Treatment Failure; Vomiting	Apo-Leflunomide	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Dorzolamide Hydrochloride;Timolol Maleate	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Estradiol	C	Unknown	Not Reported
	Estrogel	C	Unknown	Not Reported
	Furosemide	C	Unknown	Not Reported
	Morphine	C	Unknown	Not Reported
	Potassium Chloride	C	Unknown	Not Reported
	Valsartan	C	Unknown	Not Reported
	Xalatan	C	Unknown	Not Reported
	Zingiber Officinale	C	Unknown	Not Reported
	Aspirin [Acetylsalicylic Acid]	C		Not Reported
	Calcium	C		Not Reported
	Ergocalciferol	C		Not Reported
	Tiaprofenic Acid	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17526171	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-07695		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronic Acid			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Codeine			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Myochrysine	S	Intramuscular	Solution Intramuscular	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S			Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Prednisone	C	Unknown	Unknown	Not Reported
	Xeljanz	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17687239	EXPEDITED (15-DAY)		DE, LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-244297		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Ventricular Tachycardia	Azithromycin			S	Oral	250 Milligrams, Daily		Sun
	Lasilix			S	Intravenous (not otherwise specified)	2 Dosage Form, Daily		Not Reported
	Plaquenil			S	Oral	()		Not Reported
	Sufentanil			C	Intravenous (not otherwise specified)	()		Not Reported
	Perfalgan 10 Mg/Ml, Solution Pour Perfusion			C	Intravenous (not otherwise specified)	()		Not Reported
	Noradrenaline (Tartrate De)			C	Intravenous (not otherwise specified)	()		Not Reported

Midazolam	C	Intravenous (not otherwise specified)	()	Not Reported
Tazocilline	C	Intravenous (not otherwise specified)	4 Dosage Form, Daily	Not Reported
Transipeg	C	Oral	()	Not Reported
Potassium (Chlorure De)	C	Intravenous (not otherwise specified)	()	Not Reported
Effexor L.P. 37,5 Mg, Gelule A Liberation Prolongee	C	Oral	Unk	Not Reported
Ultibro Breezhaler	C	Respiratory (inhalation)	Unk	Not Reported
Seresta 10 Mg, Comprime	C	Oral		Not Reported
Rocephine	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17703365	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-019744		71 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alkalosis; Atrial Flutter; Deep Vein Thrombosis; Drug Level Increased; Enterococcal Infection; Haematuria; Haemoglobin Decreased; Hyperglycaemia; Hypoxia; Overdose; Oxygen Saturation Decreased; Quadriparesis; Staphylococcal Infection; Vascular Device Infection	Paracetamol			S	Other	4 Gram, Once A Day		Aurobindo
	Paracetamol			S				Aurobindo
	Hydroxychloroquine Sulfate			S	Unknown	800 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Other	1200 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Other	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Other	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Other	600 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Other	1000 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Other	400 Milligram, Once A Day		Not Reported
	Lovenox			S	Subcutaneous	0.6 Milliliter, Once A Day		Not Reported

	Lovenox	S	Subcutaneous	0.7 Milliliter, Once A Day	Not Reported
	Dexamethasone	C	Intravenous (not otherwise specified)	20 Milligram, Once A Day	Not Reported
	Movicol	C	Other	2 Dosage Form, Once A Day	Not Reported
	Movicol	C			Not Reported
	Lasilix	C	Parenteral	40 Milligram, Once A Day	Not Reported
	Pantoprazole	C	Oral	40 Milligram, Once A Day	Not Reported
	Pantoprazole	C			Not Reported
	Lantus	C	Subcutaneous	20 International Unit, Once A Day	Not Reported
	Tienam	C	Intravenous (not otherwise specified)	1 Gram, 3 Times A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17727385	EXPEDITED (15-DAY)		DE, HO, OT	SK-ACCORD-180080		57 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Bulbar Palsy; Cardiac Arrest; Cerebral Infarction; Dizziness; Hypotension; Intentional Product Use Issue; Jc Virus Infection; Mental Impairment; Pneumonia; Progressive Multifocal Leukoencephalopathy; Respiratory Failure; Speech Disorder; Tremor	Methotrexate			S		Unk		Accord
	Mycophenolic Acid			S				Accord
	Azathioprine/Azathioprine Sodium			S		Unk		Not Reported
	Belimumab			S		Unk		Not Reported
	Cyclophosphamide/Cyclophosphamide Monohydrate			S		Unk		Not Reported
	Ciclosporin			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Mycophenolate Mofetil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17764120	EXPEDITED (15-DAY)		DE	ES-SUN PHARMACEUTICAL		39 YR	Male	ESP

INDUSTRIES LTD-
2020RR-246394

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome; Sudden Death	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Salbutamol (2297a)			S	Respiratory (inhalation)	0.1 Milligram, 1dose/6hour		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram, Bid		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported
	Metoclopramida (1958a)			S	Intravenous (not otherwise specified)	10 Milligram, Tid		Not Reported
	Propofol (2373a)			S	Intravenous (not otherwise specified)	()		Not Reported
	Ipratropio Bromuro (1067br)			C	Respiratory (inhalation)	20 Microgram, 1dose/6hour		Not Reported
	Enoxaparina Sodica (2482so)			C	Subcutaneous	Unk		Not Reported
	Cefotaxima (3840a)			C	Intravenous drip	4 Gram, Bid		Not Reported
	Midazolam (2256a)			C	Intravenous drip	100 Milligram, Daily		Not Reported
	Tocilizumab (8289a)			C	Intravenous (not otherwise specified)	600 Milligram, Daily		Not Reported
	Tocilizumab (8289a)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17791594	EXPEDITED (15-DAY)		OT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050907			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Zydus Pharm
	Azithromycin			S				Zydus Pharm
	Dexketoprofen			S	Intravenous (not	25 Milligram Every 8		Not Reported

				otherwise specified)	Hours		
	Hidroxicloroquina [Hydroxychloroquine Sulfate]		S	Oral	400 Mg Dia		Not Reported
	Hidroxicloroquina [Hydroxychloroquine Sulfate]		S				Not Reported
	Tocilizumab		S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab		S				Not Reported
	Paracetamol		S	Oral	1 Gram Every 8 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17791595	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050817			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Qd		Zydus Pharm
	Hidroxicloroquina [Hydroxychloroquine Sulfate]			S	Oral	400 Mg Dia		Not Reported
	Hidroxicloroquina [Hydroxychloroquine Sulfate]			S				Not Reported
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Roactemra			S				Not Reported
	Lopinavir/Ritonavir			S	Oral	2u Cada 12h		Not Reported
	Lopinavir/Ritonavir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17791596	EXPEDITED (15-DAY)		DE	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050851			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Cardio-Respiratory Arrest	Azithromycin			S	Oral	500 Milligram, Qd		Zydus Pharm
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram, Single		Not Reported

	Kaletra	S	Oral	2u Cada 12h		Not Reported
	Kaletra	S				Not Reported
	Dolquine	S	Oral	400 Mg Dia		Not Reported
	Dolquine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17791597	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050909			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Zydus Pharm
	Hidroxicloroquina [Hydroxychloroquine Sulfate]			S	Oral	400 Mg Dia		Not Reported
	Hidroxicloroquina [Hydroxychloroquine Sulfate]			S				Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17791598	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050908			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Zydus Pharm
	Azithromycin			S				Zydus Pharm
	Hidroxicloroquina [Hydroxychloroquine Sulfate]			S	Oral	400 Mg Dia		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Metamizole			S	Intravenous (not otherwise specified)	2 Gram Every 6 Hours		Not Reported
	Paracetamol			S	Intravenous (not otherwise specified)	1 Gram, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17794272	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1234955		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg Day		Not Reported
	Tocilizumab (8289a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Day		Not Reported
	Ceftriaxona (501a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17794307	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1234956		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab (8289a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17794360	EXPEDITED (15-DAY)		HO, LT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247339		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia;	Azithromycin			S	Oral	500 Milligram, Daily		Sun

Pancreatitis Acute	Metilprednisolona (888a)	S	Intravenous (not otherwise specified)	250 Milligrams, Daily	Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Compri...	S	Oral	2 Dosage Form, Bid	Not Reported
	Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	1 Gram, Daily	Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S	Oral	200 Milligram, Bid	Not Reported
	Tocilizumab (8289a)	S	Intravenous (not otherwise specified)	560 Milligram, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17794364	EXPEDITED (15-DAY)		DE	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247343		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Cardio-Respiratory Arrest	Azithromycin			S	Oral	500 Mg Dia		Sun
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	In Total		Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Compri...			S	Oral	2u Cada 12h		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17794502	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050853			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hyponatraemia	Levofloxacin			S	Oral	500 Mg		Zydus Pharm
	Dolquine			S	Oral	400 Mg		Not Reported
	Kaletra			S	Oral	2 Dosage Form		Not Reported

Kaletra	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17794877	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1234795		43 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Mg		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram		Not Reported
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17795605	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050808			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg		Zydus Pharm
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab			S				Not Reported
	Hidroxicloroquina [Hydroxychloroquine]			S	Oral	400 Mg		Not Reported
	Hidroxicloroquina [Hydroxychloroquine]			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17795606	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050813			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated;	Azithromycin			S	Oral	500 Mg		Zydus Pharm

Hepatitis	Ceftriaxona [Ceftriaxone]	S	Intravenous (not otherwise specified)	2 Gram		Not Reported
	Ceftriaxona [Ceftriaxone]	S				Not Reported
	Hidroxicloroquina [Hydroxychloroquine]	S	Oral	400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17795681	EXPEDITED (15-DAY)		DS, OT	CA-SAMSUNG BIOEPIS-SB-2020-15879		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Etanercept			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Abatacept			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown			Not Reported
	Ascorbic Acid			S	Unknown	Unknown		Not Reported
	Ascorbic Acid			S	Unknown	Unknown		Not Reported
	Atenolol			S	Unknown			Not Reported
	Co Atenolol			S	Unknown			Not Reported
	Co Atenolol			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Ferrous Fumarate			S	Unknown	Unknown		Not Reported
	Ferrous Fumarate W/Folic Acid			S	Unknown	Unknown		Not Reported
	Ferrous Fumarate W/Folic Acid			S	Unknown	Unknown		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Unknown		Not Reported
Naprosyn [Naproxen]	S	Oral		Not Reported
Naprosyn [Naproxen]	S	Oral		Not Reported
Naprosyn [Naproxen]	S	Oral		Not Reported
Naproxen	S	Oral		Not Reported
Naproxen	S	Oral		Not Reported
Naproxen	S	Oral		Not Reported
Naproxen	S	Oral		Not Reported
Naproxen Sodium	S	Unknown		Not Reported
Naproxen Sodium	S	Oral		Not Reported
Naproxen Sodium	S	Oral		Not Reported
Naproxen Sodium	S	Unknown		Not Reported
Naproxen Sodium	S	Oral		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Palafer	S	Unknown	Unknown	Not Reported
Palafer Cf	S	Unknown	Unknown	Not Reported
Pantoloc	S	Unknown		Not Reported
Pantoloc	S	Unknown		Not Reported
Pantoprazole	S	Unknown		Not Reported
Pantoprazole Sodium	S	Unknown		Not Reported

Pantoprazole Sodium Anhydrous	S	Unknown			Not Reported
Pantoprazole Teva	S	Unknown			Not Reported
Pantoprazole Teva	S	Unknown	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Remicade	S	Unknown	Unknown		Not Reported
Sulfasalazine	S	Oral			Not Reported
Celebrex	C	Oral			Not Reported
Celecoxib	C	Unknown	Unknown		Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17795759	EXPEDITED (15-DAY)		OT	GB-ACCORD-181478		41 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Febrile Convulsion; Generalised Tonic-Clonic Seizure	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17795794	EXPEDITED (15-DAY)		OT	NVSC2020GB130263		23 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Encephalitis; Immune Thrombocytopenia; Liver Function Test Abnormal; Pleurisy; Systemic Lupus Erythematosus	Azathioprine			S	Unknown	150 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Prednisolone			S	Unknown	7.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17795850	EXPEDITED (15-DAY)		OT	ES-ACCORD-182145		43 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Paracetamol			S	Oral	1gr Every 8 Hours		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17795851	EXPEDITED (15-DAY)		DE, OT	ES-ACCORD-180063		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Off Label Use; Sudden Death	Tacrolimus			S	Oral			Accord
	Levofloxacin/Levofloxacin Mesylate			S	Unknown			Not Reported
	Lopinavir/Ritonavir			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin			S	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Ceftriaxone/Ceftriaxone Sodium			C	Unknown			Not Reported
	Enoxaparin			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17795856	EXPEDITED (15-DAY)		OT	SI-ACCORD-182063		50 YR	Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder; Off Label Use	Hydroxychloroquine			S	Oral	200 Mg 15.4. In The Evening And 16.4 In The Morning 400 Mg, Then 200 Mg/12 H		Not Reported
	Daleron			S	Oral	500 Mg; As Necessary, Dotal Dose Of 2 Tbl On		Not Reported

				14. And 15.4.		
	Fragmin	S	Subcutaneous	5000, 5000/24 Ur		Not Reported
	Pantoprazol Teva	C	Oral	20 Mg; 20 Mg/Day		Not Reported
	Folkodin Alkaloid-Int	C	Oral	10 Mg; As Necessary 2caps/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17795880	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597666		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Rituximab			S	Intravenous drip			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Every 1 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Risedronate	S	Unknown	Not Reported
	Risedronate	S	Unknown	Not Reported
	Risedronate Sodium	S	Oral	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17795927	EXPEDITED (15-DAY)		DE	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050898			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Levofloxacin			S	Unknown	Unk		Zydus Pharm
	Azithromycin			S	Oral	500 Milligram		Zydus Pharm
	Lopinavir/Ritonavir			S	Oral	2 Dosage Form		Not Reported
	Tacrolimus			S	Oral	Unk		Not Reported
	Hidroxicloroquina Sulfato			S	Oral	200 Milligram		Not Reported
	Prednisona			C	Oral			Not Reported
	Enoxaparina Sodica			C	Subcutaneous			Not Reported
	Ceftriaxona [Ceftriaxone]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2020	17795960	EXPEDITED (15-DAY)		DE, OT	FR-MALLINCKRODT-T202002262		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Diarrhoea; Hepatocellular Injury	Ofirmev			S	Intravenous (not otherwise specified)	4 Gram, Qd		Mallinckrodt
	Linezolide Kabi			S	Intravenous (not otherwise specified)	1200 Milligram, Qd		Not Reported
	Rovamycine			S	Intravenous (not	4.5 Mega-International		Not Reported

			otherwise specified)	Unit, Qd		
	Plaquenil	S	Oral	600 Milligram, Qd		Not Reported
	Cefotaxime	S	Intravenous (not otherwise specified)	6 Gram, Qd		Not Reported
	Movicol Plain	C	Unknown	Unk		Not Reported
	Amikacine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17629401	NON-EXPEDITED			US-AMGEN-USASP2020048450		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, 0, 2, 6 Wks, Then Every 8 Wks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 8 Weeks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 7 Weeks		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Otrexup			S	Unknown	Unk		Not Reported
	Otrexup			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17691077	EXPEDITED (15-DAY)		HO	CA-ROCHE-2584754			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Off Label Use; Product Label Confusion; Treatment Failure; Vomiting	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Arava		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Intravenous (not otherwise specified)	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulphate		S	Oral	Not Reported
	Cimzia		C	Subcutaneous	Not Reported
	Enbrel		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17796047	EXPEDITED (15-DAY)		HO, LT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050911			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia; Pancreatitis Acute	Azithromycin			S	Oral	500 Milligram, Qd		Zydus Pharm
	Methylprednisolone			S	Intravenous (not otherwise specified)	250 Milligram		Not Reported
	Kaletra			S	Oral	2 Dosage Form		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Dolquine			S	Oral	200 Milligram		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	560 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17796048	EXPEDITED (15-DAY)		OT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Long Qt Syndrome	Azithromycin			S	Unknown	Unk		Zydus Pharm
	Propofol			S	Unknown	Unk		Not Reported
	Propofol			S				Not Reported
	Dolquine			S	Oral	200 Milligram		Not Reported
	Midazolam			S	Unknown			Not Reported
	Midazolam			S				Not Reported
	Kaletra			S	Oral	Unk		Not Reported
	Ceftriaxona [Ceftriaxone]			S	Unknown	Unk		Not Reported
	Omnic Ocas			C	Unknown			Not Reported
	Simvastatina			C	Unknown			Not Reported
	Cortica			C	Unknown	Corticoides A Dosis Bajas		Not Reported
	Kalpress			C	Unknown	Unk		Not Reported
	Manidon Hta			C	Unknown	Unk		Not Reported
	Rilast			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17796097	EXPEDITED (15-DAY)		DE	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-02		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Combivent			S	Unknown	Form Of Admin: Solution Inhalation		Boehringer Ingelheim
	Alendronate Sodium			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Lasix [Furosemide]			S	Unknown			Not Reported
	Lipitor [Atorvastatin]			S	Unknown			Not Reported

	Losec [Omeprazole]	S	Unknown	Not Reported
	Metformin	S	Unknown	Not Reported
	Nitrazadon	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Salmeterol Xinafoate	S	Unknown	Not Reported
	Tylenol	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17796127	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235371			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Simponi			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	11042903	EXPEDITED (15-DAY)		OT	CA-ROCHE-1565162		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Arthralgia; Arthralgia; Arthropathy; Drug Ineffective; Drug Ineffective; Fatigue; Groin Pain; Joint Injury; Joint Range Of Motion Decreased; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Pain; Pain In Extremity; Pain In Extremity; Peripheral Swelling; Retinal Toxicity; Rheumatoid Arthritis; Sleep Disorder; Swelling; Swelling	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 990.0 Nos		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Xeljanz			C	Oral			Not Reported
	Tramadol Hcl			C	Oral			Not Reported
	Rabeprazole Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	12905295	EXPEDITED (15-DAY)		OT	CA-ROCHE-1624144		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Impaired Work Ability; Nasopharyngitis; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased;	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Therapeutic Product Effect Incomplete	Humira	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Vioxx	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Wellbutrin	C		Not Reported
	Sulfasalazine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	12974330	EXPEDITED (15-DAY)		OT	CA-ROCHE-1858733			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Ill-Defined Disorder; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported

	Xeljanz	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	13011431	EXPEDITED (15-DAY)		OT	CA-ROCHE-1865032		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Abatacept			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Therapy Duration: 486.0 Nos		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Prednisolone	C	Unknown	Not Reported
	Azathioprine	C	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Minocycline	C	Unknown	Not Reported
	Penicillamine	C		Not Reported
	Prednisone	C	Unknown	Not Reported
	Tocilizumab	C	Unknown	Not Reported
	D-Penicillamine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	13045102	EXPEDITED (15-DAY)		OT	CA-ROCHE-1869641		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Folinic Acid			C	Unknown			Not Reported
	Apo-Hydroxyquine			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

	Calcium		C	Unknown	Not Reported
	Leucovorin [Folinic Acid]		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	13132261	EXPEDITED (15-DAY)		OT	CA-ROCHE-1619414		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Intolerance; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 987 Days		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Lyrica			S	Oral			Not Reported
	Xeljanz			S	Oral	Therapy Duration: 2 Years		Not Reported
	Xeljanz			S	Oral	Therapy Duration: 3 Months		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	13316486	EXPEDITED (15-DAY)		OT	CA-ROCHE-1808908			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Burning Sensation; Colitis; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Actemra	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	13663116	EXPEDITED (15-DAY)		OT	CA-ROCHE-1951182		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Treatment Failure; Tremor	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 9 Months		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Pantoprazole Magnesium	C	Unknown	Not Reported
Tenofovir Disoproxil	C	Unknown	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Zopiclone	C	Unknown	Not Reported
Methotrexate	C	Oral	Not Reported
Tenofovir	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	14058071	EXPEDITED (15-DAY)		OT	CA-SA-2017SA182819		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise;	Plaquenil			S	Oral	200 Mg,Bid		Sanofi
	Arava			S	Oral	20 Mg,Qd		Sanofi
	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Paracetamol			S	Unknown	Unk Unk,Prn		Not Reported
	Paracetamol			S				Not Reported
	Paracetamol			S		325 Mg		Not Reported
	Sulfasalazine			S	Oral	2000 Mg,Unk		Not Reported
	Acetaminophen;Diphenhydramine Hydrochloride			S				Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	50 Mg,Qw		Not Reported

Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Somnolence; Visual Impairment	Humira	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Orencia	S		Unk Unk,Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Simponi	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Tylenol	C			Not Reported
	Codeine Phosphate	C	Unknown	Unk Unk,Unk	Not Reported
	Leflunomide	C	Unknown	20 Mg, Qd	Not Reported
	Celebrex	C	Oral	200 Mg,Bid	Not Reported
	Hydromorphone Hcl	C			Not Reported
	Acetaminophen;Codeine Phosphate	C			Not Reported
	Hydromorph	C	Unknown	Unk Unk,Prn	Not Reported
	Methotrexate	C	Unknown	25 Mg,Qw	Not Reported
	Synthroid	C		Unk Unk,Unk	Not Reported
	Meloxicam	C		Unk Unk,Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	14165914	EXPEDITED (15-DAY)		OT	CA-SA-2017SA210506		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell	Arava			S	Oral	20 Mg,Qd		Sanofi
	Paracetamol			S	Unknown	Unk Unk,Unk		Not Reported
	Sulfasalazine			S	Oral	Unk Unk,Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg,Bid		Sanofi
	Paracetamol			S		325 Mg		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	50 Mg,Qw		Not Reported

Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Humira		S	Subcutaneous	Unk Unk,Unk	Not Reported
	Orencia		S	Unknown	Unk Unk,Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Simponi		S	Subcutaneous	Unk Unk,Unk	Not Reported
	Meloxicam		C	Unknown		Not Reported
	Methotrexate		C	Unknown	25 Mg/Ml, Qw	Not Reported
	Acetaminophen And Codeine Phosphate		C	Unknown	Unk, Unk	Not Reported
	Synthroid		C		Unk Unk,Unk	Not Reported
	Tylenol [Paracetamol]		C			Not Reported
	Leflunomide		C	Unknown	20 Mg, Qd	Not Reported
	Celebrex		C			Not Reported
	Hydromorphone Hcl		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	15100628	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0716		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Kineret			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Apo-Azathioprine			S	Vaginal			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Imuran			S	Unknown			Not Reported

	Methotrexate Sodium	S		Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Cimzia	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Certolizumab Pegol	S		Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	15394598	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184764		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Arthrotec	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Imuran [Azathioprine]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	15755439	EXPEDITED (15-DAY)		DS, HO, OT	CA-ROCHE-2229884			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Etanercept	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Azathioprine	C	Unknown	Not Reported
	Imuran [Azathioprine]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	16005011	EXPEDITED (15-DAY)		HO, OT	CA-SA-2015SA139124		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S				Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk Unk,Unk		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Kineret			S	Unknown	Unk Unk,Unk		Not Reported
	Kineret			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Simponi			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown	Unk Unk,Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported

Gold	S	Unknown			Not Reported
Celebrex	C	Unknown	Unk Unk,Unk		Not Reported
Methotrexate	C	Unknown	Unk Unk,Unk		Not Reported
Prednisone	C	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
Humira	C	Subcutaneous	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	16095354	EXPEDITED (15-DAY)		OT	CA-BECTON DICKINSON-2019BDN00113		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blister; Confusional State; Contraindicated Product Administered; Contusion; Drug Ineffective; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Off Label Use; Peripheral Swelling; Pruritus; Pyrexia; Rash; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Weight Increased	Chloraprep			S	Topical			Becton Dickinson
	Chlorhexidine			S				Becton Dickinson
	Chlorhexidine Gluconate			S				Becton Dickinson
	Abatacept			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S				Not Reported
	Acetaminophen/Oxycodone Hydrochloride			S				Not Reported
	Acetaminophen/Oxycodone Hydrochloride/Oxycodone Terephthalate			S				Not Reported
	Act Oxycodone Cr			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728.0 Mg, 1x/Month		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Mg, 1x/Month		Not Reported
	Actemra			S		Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728.0 Mg; 4 Every 1 Week		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Mg; 4 Every 1 Week		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728.0 Mg, Unk		Not Reported

Actemra	S	Intravenous (not otherwise specified)	752.8 Mg, Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	752.8 Mg, 1 Every 4 Week(S)	Not Reported
Actemra	S	Intravenous (not otherwise specified)	728 Mg, 1 Every 4 Week(S)	Not Reported
Actemra	S	Intravenous (not otherwise specified)	728.0 Mg, 1x/Month	Not Reported
Actemra	S	Intravenous (not otherwise specified)	752.8 Mg, 1x/Month	Not Reported
Actemra	S	Intravenous (not otherwise specified)	725 Mg, Every 4 Weeks	Not Reported
Apo-Acetaminophen	S			Not Reported
Chlorhexidine Gluconate Oral Rinse	S			Not Reported
Cimzia	S	Subcutaneous		Not Reported
Cimzia Single-Use Pre-Filled Syringe	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Enbrel	S		Unk	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Leflunomide	S			Not Reported
Methotrexate	S			Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate Sodium	S			Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Oxycodone	S			Not Reported
Oxycodone-Acetaminophen	S			Not Reported
Oxycodone Cr	S			Not Reported
Oxycodone Hydrochloride	S			Not Reported
Oxycodone Terephthalate	S			Not Reported
Periogard	S			Not Reported
Periogard Alcohol Free	S	Buccal		Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Periarticular	Unk	Not Reported

Sulfamethoxazole	S			Not Reported
Sulfamethoxazole/Trimethoprim	S			Not Reported
Arava	C	Oral	20 Mg, 1x/Day	Not Reported
Arava	C		Unk	Not Reported
Cetirizine	C			Not Reported
Cetirizine Hydrochloride	C			Not Reported
Desogestrel/Ethinyl Estradiol	C			Not Reported
Hydroxychloroquine Phospate	C			Not Reported
Hydroxychloroquine Sulfate	C		400 Mg, 1x/Day	Not Reported
Ibuprofen	C			Not Reported
Pantoloc	C			Not Reported
Pantoprazole	C			Not Reported
Pantoprazole Sodium	C			Not Reported
Paracetamol	C			Not Reported
Paracetamol/Codeine	C			Not Reported
Plaquenil	C			Not Reported
Prednisone	C	Oral	7.5 Mg, 1x/Day	Not Reported
Prednisone	C		Unk	Not Reported
Reactine	C		10 Mg, 2x/Day	Not Reported
Reactine	C		Unk	Not Reported
Tylenol	C			Not Reported
Tylenol With Codeine	C			Not Reported
Tylenol #1	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	16438452	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-15073			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Etanercept			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported

Actemra	S	Unknown	Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Arava	S	Unknown	Unknown	Not Reported
Arava	S	Oral	Unknown	Not Reported
Cimzia	S	Subcutaneous	Unknown, Solution Subcutaneous, Single-Use Pre-Filled Syringe	Not Reported
Desoximetasone	S	Unknown	Unknown	Not Reported
Desoximetasone	S	Oral	Unknown	Not Reported
Folic Acid	S	Unknown	Unknown	Not Reported
Folic Acid	S			Not Reported
Fosamax	S	Unknown	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Unknown	Not Reported
Methotrexate	S	Unknown	Unknown	Not Reported
Methotrexate	S			Not Reported
Orencia	S	Subcutaneous	Unknown	Not Reported
Prednisone	S	Unknown	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unknown, Solution Intravenous	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Simponi	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
Simponi	S	Subcutaneous	Unknown	Not Reported
Sulfasalazine	S	Unknown	Unknown	Not Reported
Enbrel	S	Unknown	Unknown	Not Reported
Enbrel	S			Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported

	Cetirizine Hydrochloride	S	Unknown	Unknown		Not Reported
	Cetirizine	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	16936539	EXPEDITED (15-DAY)		OT	CA-ROCHE-2436270		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17063576	EXPEDITED (15-DAY)		HO	CA-ROCHE-2472424			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17070136	EXPEDITED (15-DAY)		HO	CA-ROCHE-2474304			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not	Powder For Solution		Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17258667	EXPEDITED (15-DAY)		OT	CA-ROCHE-2513921		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Other			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17310605	EXPEDITED (15-DAY)		OT	CA-009507513-2001CAN007489		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand	Fosamax			S	Unknown	Unk		Merck
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Solution For Injection In Pre-Filled Pen		Merck

Deformity; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Simponi	S	Subcutaneous	Unk	Merck
	Actemra	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Apo Prednisone	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride (+) Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	400 Milligram; Solution For Injection In Pre-Filled Syringe	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S		25 Milligram	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	5.0 Milligram	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	Formulation: Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	20.0 Milligram, Qd (1 Every 1 Day)	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Oral	25 Milligram 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, 1 Every 1 Weeks	Not Reported

Methotrexate	S	Intra-arterial	25 Milligram, 1 Every 1 Weeks	Not Reported
Methotrexate	S	Unknown	20 Milligram, 1 Every 1 Days	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	400.0 Milligram, Qd (1 Every 1 Day)	Not Reported
Plaquenil	S			Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	40 Milligram	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Oral	1000.0 Milligram, Bid (2 Every 1 Day)	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram, 2 Every 1 Day	Not Reported
Sulfasalazine	S	Subcutaneous	500 Milligram	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Apo Folic Acid	S	Unknown		Not Reported
Prednisone	S	Oral		Not Reported
Diclofenac	C	Unknown	50 Milligram	Not Reported

	Diclofenac		C	Unknown	Unk	Not Reported
	Salazopyrin		C	Unknown	Unk	Not Reported
	Salazopyrin		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17723898	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020169257		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	1 Df, Daily		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	600 Mg, 1x/Day		Not Reported
	Atrovent			C	Respiratory (inhalation)	3 Df, Daily		Not Reported
	Bricanyl			C		3 Df, Daily		Not Reported
	Lovenox [Enoxaparin Sodium]			C	Subcutaneous	Unk		Not Reported
	Coversyl [Perindopril Arginine]			C	Oral	1 Df, Daily		Not Reported
	Perfalgan			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17755163	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592591		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain;	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Abatacept			S	Unknown	7.0 Months		Not Reported
	Adalimumab			S	Unknown	9.0 Years		Not Reported
	Ciclosporin			S	Unknown			Not Reported

Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Cyclosporine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17763811	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593629			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Gait Inability; Joint Swelling; Mobility Decreased; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Tramadol			S	Unknown			Not Reported
	Tramadol Hydrochloride			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

	Prednisone	C	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17790725	EXPEDITED (15-DAY)		DE, OT	IT-ABBVIE-20K-083-3402967-00		59 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Gamma-Glutamyltransferase Increased; Hepatotoxicity; Hypertransaminasaemia; Off Label Use; Septic Shock	Kaletra			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17796741	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA123205			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis;	Arava			S	Unknown	Unk		Sanofi
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Diclofenac			S	Topical	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Sulfamethoxazole/Trimethoprim			S	Unknown			Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported

Vomiting; Weight Decreased	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Gold Sodium Thiomalate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Tramadol Hydrochloride	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17796742	EXPEDITED (15-DAY)		OT	CA-SA-2020SA123089			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Ineffective; Drug Intolerance; Feeding Disorder; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Leflunomide			S	Unknown	20 Mg		Sanofi
	Hydroxychloroquine			S	Unknown	400 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Varenicline Tartrate			S	Oral	1 Df, Qd		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg		Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Oxycodone Hydrochloride			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Rosuvastatin Calcium			C	Unknown	Unk		Not Reported
	Tofacitinib Citrate			C	Unknown	Unk		Not Reported
	Valtrex			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17796745	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA123222			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Pain; Nausea; Neck Pain; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rash; Therapeutic Product Effect Decreased; Weight Decreased	Arava			S	Oral	20 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 2 Every 1 Day		Sanofi
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Prednisone			S	Oral	5 Mg, 1 Every 1 Day		Not Reported
	Sulfasalazine			S		1000 G, 2 Every 1 Day		Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Humira			S		20 Mg, 1 Every 1 Day		Not Reported
	Orencia			S		Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17796746	EXPEDITED (15-DAY)		OT	CA-SA-2020SA122659		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product Administration; Inappropriate Schedule Of Product Administration; Liver Function Test Increased; Rash; Rheumatoid Arthritis	Arava			S				Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Humira			S		40 Mg		Not Reported

	Orencia	S		125 Mg, Qw	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 G	Not Reported
	Simponi	C	Subcutaneous	50 Mg, Qm	Not Reported
	Prednisone	C		Unk	Not Reported
	Sulfasalazine	C		Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17796747	EXPEDITED (15-DAY)		OT	ES-SA-2020SA124226		62 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Hypocoagulable State; Hypofibrinogenaemia; Thrombocytopenia	Enoxaparin Sodium			S	Subcutaneous	80 Mg		Sanofi
	Enoxaparin Sodium			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Oral	400 Mg Day		Sanofi
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Mg		Not Reported
	Dexamethasone			S	Unknown	Unk		Not Reported
	Azithromycin			S	Oral	500 Mg Day		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gr Day		Not Reported
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17796759	EXPEDITED (15-DAY)		OT	CA-SA-2020SA122582			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Off Label Use;	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Sanofi
	Enbrel			S	Unknown	Unk		Not Reported

Rheumatoid Arthritis; Treatment Failure; Vomiting	Infliximab		S	Unknown	Unk		Not Reported
	Orencia		S	Unknown	Unk		Not Reported
	Morphine		C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17796995	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600501			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Off Label Use; Weight Increased	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Levothyroxine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17797026	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596275			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Interstitial Lung Disease; Joint Swelling; Musculoskeletal Stiffness	Rituximab			S	Intravenous drip	Therapy Duration: 403.0 Days		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Therapy Duration: 0.0		Not Reported
	Mycophenolate Mofetil			S	Oral			Not Reported
	Adalimumab			S	Subcutaneous	Therapy Duration: 8.0 Years		Not Reported
	Imuran [Azathioprine]			S	Unknown	Therapy Duration: 21.0 Years		Not Reported

	Infliximab	S	Intravenous (not otherwise specified)	Therapy Duration: 6.0 Months	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Therapy Duration: 31.0	Not Reported
	Glyburide	C	Oral		Not Reported
	Infliximab	C	Unknown		Not Reported
	Lipitor [Atorvastatin Calcium]	C	Unknown		Not Reported
	Metformin	C	Oral		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17797182	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235401			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Acetaminophen			S	Unknown			Not Reported
	Propofol			S	Unknown			Actavis
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17797231	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600590		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Off	Rituximab			S	Intravenous (not			Not Reported

Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance			otherwise specified)		
	Arava	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17797302	EXPEDITED (15-DAY)		OT	BR-ADVANZ PHARMA-202004004827			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Endotracheal Intubation; Mechanical Ventilation; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Azithromycine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17797376	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202005005211			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia; Off Label Use	Hydroxychloroquine			S	Oral	200 Mg, Qd		Concordia
	Hydroxychloroquine			S	Oral	200 Mg, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17797559	EXPEDITED (15-DAY)		OT	NVSC2020PH132416		80 YR	Female	PHL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication; Suspected Covid-19	Azithromycin			S	Oral	0.5 Df (250 Mg), Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17797999	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247406		45 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia	Azithromycin			S	Unknown	Unk		Sun
	Kaletra			S	Unknown	Unk		Not Reported
	Interferon Beta-1b (2305od)			S	Unknown	Unk		Not Reported
	Ceftriaxona (501a)			S	Unknown	Unk		Not Reported
	Hidroxicloroquina (2143a)			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798034	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598836		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Neoral	S	Oral	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C		Not Reported
	Sulfasalazine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798156	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1228873		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798212	EXPEDITED (15-DAY)		DE	ES-BAUSCH-BL-2020-014076		26 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy	Dexametasona			S	Intravenous (not otherwise specified)	20 Mg Dia		Bausch And Lomb
	Enoxaparina			S	Subcutaneous	40mg Dia		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	Total Dose: 600 Mg		Not Reported
	Tocilizumab			S				Not Reported
	Dexketoprofeno			S	Intravenous (not otherwise specified)	25 Mg Every 8 Hours		Not Reported
	Hidroxicloroquina			S	Oral	400 Mg Dia		Not Reported
	Azitromicina			S	Oral	500 Mg Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798226	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235250			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798348	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20200503968			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy	Otezla			S	Unknown			Celgene
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798480	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1235771		82 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Generalised Exanthematous Pustulosis; Erythema	Darunavir		S	Oral	1 Dosage Forms	Teva
	Colchicina Lirca		S	Oral	1 Dosage Forms	Not Reported
	Plaquenil		S		2 Dosage Forms	Not Reported
	Ritonavir Sandoz		S	Oral	1 Dosage Forms	Not Reported
	Clexane		C			Not Reported
	Pradaxa 150mg Hard Capsules		C			Not Reported
	Lasix 25 Mg Compresse		C			Not Reported
	Bisoprolol Fumarate		C			Not Reported
	Zopranol		C	Oral		Not Reported
	Cordarone 200 Mg Compresse		C			Not Reported
	Omeprazole		C			Not Reported
	Enoxaparin Sodium		C	Subcutaneous	4000 Ku	Not Reported
	Symbicort, 160 Microgrammi/4,5 Microgrammi/ Inalazione, Polvere Per In		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798522	EXPEDITED (15-DAY)		OT	BE-MYLANLABS-2020M1047718		83 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Trazodone			S		1/4 Tablet In The Morning And At Noon And 1/2 Tablet In The Evening		Not Reported
	Trazodone			S		Unk		Not Reported
	Plaquenil /00072603/			S	Oral	Day 1: 400mg 2x/D Day 2-4: 200mg 1x/D 7/04 : Received 2x 400 Mg 08/04 To 10/04		Mylan
	Zyprexa			S		Unk		Mylan
	Zyprexa			S		1/2 Tablet 2x/Day Treatment Was Suspended For 2 Days 11/04 And 12/04 And Then Resumed		Mylan
	Algostase Mono			C		1 Df, Tid		Mylan

	Contramal	C		Unk Unk, Prn	Mylan
	Pradaxa	C		Unk	Mylan
	Movicol /01749801/	C		1 Df, Qd	Mylan
	Uni Diamicron	C		60 Mg, Bid	Mylan
	L-Thyroxine /00068001/	C		150 Ug, Qd	Mylan
	Metformin	C		500 Mg, Bid	Mylan
	Magnetop /00434501/	C	Oral	450 Mg, Qd	Mylan
	Clexane	C		Unk	Mylan
	Perindopril	C		2 Mg, Qd	Mylan
	Kalium /00031401/	C		600 Mg	Mylan
	Prolopa	C		0.5 Df, Qd	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798528	EXPEDITED (15-DAY)		HO	FR-NATCO PHARMA-2020NAT00018		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Musculoskeletal Toxicity	Chloroquine Phosphate			S	Unknown	200 Mg, 1x/Day		Natco Pharma
	Hydroxychloroquine			S	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown	75 Mg, 1x/Day		Not Reported
	Clopidogrel			C	Unknown	75 Mg, 1x/Day		Not Reported
	Fenofibrate			C	Unknown	100 Mg, 1x/Day		Not Reported
	Ranitidine			C	Unknown	300 Mg, 1x/Day		Not Reported
	Clobetasol			S	Unknown	1 Application/Day		Not Reported
	Paracetamol/Tramadol			C	Unknown	If Necessary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798599	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1235508		48 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypofibrinogenaemia;	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva

Pulmonary Embolism	Roactemra	S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Azitromicina (7019a)	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798648	EXPEDITED (15-DAY)		OT	CA-SA-2020SA123042		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Headache; Migraine; Off Label Use; Product Use Issue; Respiratory Tract Infection; Therapeutic Product Effect Incomplete; Urinary Tract Infection; White Blood Cell Count Decreased	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Arava			S	Unknown	10 Mg, Qd		Sanofi
	Arava			S	Unknown	10 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qod		Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Anakinra			S		Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798652	EXPEDITED (15-DAY)		OT	CA-SA-2020SA122868		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Hydroxychloroquine			S	Subcutaneous	Unk		Sanofi
	Methotrexate			S	Oral	20 Mg		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Leflunomide			S		Unk		Sanofi
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Neoral			S	Subcutaneous	Unk		Not Reported

Orencia	S	Subcutaneous	125 Mg		Not Reported
Remicade	S		3 Mg		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Xeljanz	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798666	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1047766		49 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Off Label Use; Rash; Rash Maculo-Papular	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Dosage Form, Qd		Not Reported
	Lopinavir/Ritonavir			S	Oral	4 Dosage Form, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798669	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1047777		78 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Long Qt Syndrome	Azithromycin			S	Unknown	No Especificada		Not Reported
	Propofol			S	Unknown	Unk		Mylan
	Propofol			S				Mylan
	Dolquine			S	Oral	Un Comprimido Desayuno Y Cena		Mylan
	Midazolam			S	Unknown	Unk		Mylan
	Midazolam			S				Mylan
	Kaletra			S	Oral	Unk		Mylan
	Ceftriaxona /00672201/			S	Unknown	No Especificada		Mylan
	Manidon Hta			C		Unk		Mylan
	Rilast			C		Unk		Mylan
	Omnic Ocas			C		Unk		Mylan

Simvastatina	C	Unk	Mylan
Kalpress	C	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798804	EXPEDITED (15-DAY)		OT	CA-SA-2020SA123322			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Lower Respiratory Tract Infection; Neck Pain; Pain In Extremity; Peripheral Swelling	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	300 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798828	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1047791		58 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase; Hypertransaminasaemia; Off Label Use	Piperacillin/Tazobactam			S	Intravenous (not otherwise specified)	1 Dosage Form, Qd		Not Reported
	Kaletra			S	Oral	4 Dosage Form, Qd		Mylan
	Plaquenil /00072602/			S	Oral	400 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798848	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235389		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy;	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Piroxicam			S	Unknown			Not Reported

Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Pregabalin		S	Oral	Teva
	Actemra		S	Subcutaneous	Not Reported
	Arava		S	Oral	Not Reported
	Enbrel		S	Unknown	Not Reported
	Gold		S	Unknown	Not Reported
	Humira		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab/Vorhyaluronidase Alfa		S	Subcutaneous	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sodium Aurothiomalate		S	Parenteral	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798851	EXPEDITED (15-DAY)		DE, HO	ES-TEVA-2020-ES-1235527		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Hypofibrinogenaemia; Upper Gastrointestinal Haemorrhage	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva
	Linezolid (1279a)			S	Intravenous (not otherwise specified)	1200 Milligram Daily;		Teva
	Piperacilina Tazobactam 4g/0,5g			S	Intravenous (not otherwise specified)	1 Dosage Form, C/8h		Not Reported
	Roactemra 20 Mg/Ml, Concentrado Para Solucion Para Perfusion			S		600mg		Not Reported
	Roactemra 20 Mg/Ml, Concentrado Para Solucion Para Perfusion			S				Not Reported
	Meropenem (7155a)			S	Intravenous (not	3 Gram Daily;		Not Reported

	Metamizol (111a)			S	otherwise specified) Intravenous (not otherwise specified)	6 Gram Daily;			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798855	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235812		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Exposure Before Pregnancy; Maternal Exposure During Pregnancy; Placental Insufficiency; Premature Delivery	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Immune Globulin (Human)			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798978	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235384		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Musculoskeletal Stiffness; Pain; Pulmonary Fibrosis	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17799003	EXPEDITED (15-DAY)		OT	ES-ALLERGAN-2019800US			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatitis	Fosfomycin Tromethamine - Bp	S	Oral	3 G, Qd		Allergan
	Azitromicina	S	Oral	500 Mg, Qd		Not Reported
	Azitromicina	S				Not Reported
	Cefixima	S	Oral	400 Mg, Qd		Not Reported
	Hidroxicloroquina	S	Oral	400 Mg, Qd		Not Reported
	Hidroxicloroquina	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17799007	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1235779		48 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Paracetamol (12a)			S	Oral	3 Gram Daily; 1gr Every 8 Hours		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Cefditoreno Pivoxilo (7358ps)			S	Oral	800 Milligram Daily; 400 Mg Every 12 Hours		Not Reported
	Cefditoreno Pivoxilo (7358ps)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17799090	EXPEDITED (15-DAY)		DE, OT	ES-TEVA-2020-ES-1235781		62 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Hypocoagulable State; Hypofibrinogenaemia; Thrombocytopenia	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Dexametasona (722a)			S	Intravenous (not otherwise specified)	20 Mg		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Enoxaparina (2482a)			S	Subcutaneous	80 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17799099	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235652		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Alendronate Sodium			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral	20 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Plaquenil	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfathalidine	S	Unknown		Not Reported
	Diclofenac	C	Unknown		Not Reported
	Salazopyrin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17799108	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1235526		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Colchicina (142a)			S	Oral	1 U Breakfast		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab (8289a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17799283	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235458		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Prednisone		S	Oral	5 Milligram Daily;	Actavis
	Methotrexate		S	Subcutaneous		Barr
	Methotrexate		S	Subcutaneous		Barr
	Actemra		S	Unknown		Not Reported
	Apo-Prednisone		S	Oral	5 Milligram Daily;	Not Reported
	Arava		S	Unknown	20 Milligram Daily;	Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous	20 Milligram Daily;	Not Reported
	Hydroxychloroquine		S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram Daily;	Not Reported
	Orencia		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown	2000 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17799351	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1235378		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Blood Glucose Abnormal; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Secretion Discharge; Sputum Discoloured; Thrombosis	Prednisone			S	Unknown	20 Milligram Daily;		Actavis
	Prednisone			S	Unknown	20 Milligram Daily;		Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

			otherwise specified)		
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Warfarin Sodium	S	Unknown		Not Reported
	Warfarin Sodium	S	Unknown		Not Reported
	Amitriptyline	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17799352	EXPEDITED (15-DAY)		OT	RO-MYLANLABS-2020M1002236		66 YR	Male	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia; Product Use In Unapproved Indication	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Mylan
	Azathioprine			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17799392	EXPEDITED (15-DAY)		OT	ES-BIODELIVERY SCIENCES INTERNATIONAL-2020BDSI0343		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Tinnitus	Fentanyl Citrate			S	Unknown			Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported
	Ritonavir/Lopinavir			S	Oral	(5 Ml/12h)		Not Reported
	Midazolam			S	Unknown			Not Reported

	Hydroxychloroquine		S	Oral	200mg/12h	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17799618	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1048632		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Hidroxicloroquina /00072601/			S	Oral	400 Mg Dia		Mylan
	Hidroxicloroquina /00072601/			S				Mylan
	Roactemra			C	Intravenous (not otherwise specified)	600 Mg		Mylan
	Roactemra			C				Mylan
	Ceftriaxona /00672201/			C	Intravenous (not otherwise specified)	2 Gr Dia		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17799620	EXPEDITED (15-DAY)		DE	ES-MYLANLABS-2020M1048589		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Cardio-Respiratory Arrest	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram, Total		Mylan
	Kaletra			S	Oral	2 Dosage Form, Bid		Mylan
	Kaletra			S				Mylan
	Dolquine			S	Oral	400 Milligram, Qd		Mylan
	Dolquine			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17799624	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1048642		57 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, (500 Mg		Not Reported

					Dia)	
	Lopinavir/Ritonavir		S	Oral	Unk, Bid, (2u Cada 12h)	Not Reported
	Lopinavir/Ritonavir		S			Not Reported
	Roactemra		S	Intravenous (not otherwise specified)	600 Mg	Mylan
	Roactemra		S			Mylan
	Hidroxicloroquina /00072601/		S	Oral	400 Mg Dia	Mylan
	Hidroxicloroquina /00072601/		S			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17799987	EXPEDITED (15-DAY)		HO, OT	ES-ABBVIE-20K-144-3400696-00		11 YR	Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Infection; Off Label Use; Shock	Lopinavir/Ritonavir			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801751	DIRECT	Y	LT			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine Sulfate			S	Oral	Other Frequency:Bid X1day,Then Qd;		Sandoz
	Meropenem 500mg Iv			C				Not Reported
	Acetaminophen 650mg Po			C				Not Reported
	Aspirin 81mg Po			C				Not Reported
	Atorvastatin 40mg Po			C				Not Reported
	Enoxaparin 40mg Sc			C				Not Reported
	Gabapentin 300mg Po			C				Not Reported
	Hydroxychlorothiazide 25mg Po			C				Not Reported
	Levothyroxine 25 Mcg Po			C				Not Reported
	Lisinopril 40mg Po			C				Not Reported
	Sertraline 50mg			C				Not Reported

	Azithromycin 500mg Iv	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801911	DIRECT						Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	11179339	EXPEDITED (15-DAY)		OT	CA-ROCHE-1590696		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Swelling; Candida Infection; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Drug Interaction; Drug Interaction; Hepatotoxicity; Joint Swelling; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nausea; Neoplasm Malignant; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Rheumatoid Arthritis; Swelling; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Thyroid	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Therapy Duration: 3 Years		Not Reported
	Leflunomide			S	Oral	Therapy Duration: 9 Months		Not Reported
	Leflunomide			S	Oral			Not Reported
	Sulfasalazine			S	Unknown	Therapy Duration: 3 Years		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	Therapy Duration: 13 Years		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Neoplasm; Thyroid Neoplasm; Toxicity To Various Agents; Toxicity To Various Agents	Methotrexate		S	Subcutaneous	Not Reported
	Apo-Leflunomide		S	Oral	Not Reported
	Apo-Leflunomide		S	Oral	Not Reported
	Apo-Leflunomide		S	Oral	Not Reported
	Apo-Prednisone		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Actemra		S	Subcutaneous	Not Reported
	Humira		S	Unknown	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	12117854	EXPEDITED (15-DAY)		OT	CA-ROCHE-1630803		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort; Back Pain; Blood Pressure Increased; Bone Disorder; Contusion; Crying; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage; Hypersensitivity; Immune System Disorder; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Osteoarthritis; Osteoporosis; Pain; Pruritus; Rash; Swelling	Actemra			S	Unknown	Stopped		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Stopped.		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	12146308	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2016130747		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Pantoloc			S	Unknown	40 Milligram, Qd		Pfizer
	Pantoloc			S	Unknown	40 Milligram, Qd		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Etanercept			S		Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, Q2weeks		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, 1/Week		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, 1/Week		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, 1/Week		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, Q2weeks		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, Q2weeks		Pfizer
	Methotrexate Sodium			S	Oral	Unk, Q2weeks		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, Qd		Pfizer
	Sulfasalazine			S	Oral	500 Milligram, Bid		Pfizer
	Sulfasalazine			S	Oral	1000 Milligram, Bid		Pfizer
	Sulfasalazine			S	Oral	500 Milligram, Bid		Pfizer
	Pantoprazole Sodium Anhydrous			S		40 Mg, 1x/Day		Not Reported
	Pantoprazole Sodium Sesquihydrate			S		40 Mg, 1x/Day		Not Reported
	Apo-Folic Acid			S		5 Mg, 2x/Week		Not Reported
	Apo-Folic Acid			S		5 Mg, 2x/Week		Not Reported
	Co Atenolol			S		25 Milligram, Qd		Not Reported
	Co Atenolol			S		20 Milligram, Qd		Not Reported
	Atenolol			S		25 Mg, 1x/Day		Not Reported
	Naprosyn			S	Oral	100 Milligram, Qd		Not Reported

Naprosyn	S	Oral	500 Milligram, Bid	Not Reported
Naprosyn	S	Oral	500 Mg, 2x/Day	Not Reported
Naprosyn	S	Oral	1000 Mg, 1x/Day	Not Reported
Naproxen	S	Oral	100 Milligram, Qd	Not Reported
Naproxen	S	Oral	500 Milligram, Qd	Not Reported
Naproxen	S	Oral	500 Milligram, Bid	Not Reported
Palafer Cf	S	Unknown	Unk, Qd	Not Reported
Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
Plaquenil	S	Unknown	400 Milligram, Qd	Not Reported
Plaquenil	S	Unknown	40 Milligram, Qd	Not Reported
Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
Pantoprazole Teva	S	Unknown	40 Milligram, Qd	Not Reported
Pantoprazole Teva	S	Unknown	Unk	Not Reported
Ferrous Fumarate W/Folic Acid	S	Unknown	Unk Unk, Qd	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Arava	S	Oral	Unk	Not Reported
Leflunomide	S	Oral	20 Mg, 1x/Day	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	Unk, Qd	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S		Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Abatacept	S		Unk	Not Reported
Ascorbic Acid	S		Unk, 1x/Day	Not Reported
Ferrous Fumarate	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	5 Milligram, Bid	Not Reported
Folic Acid	S	Unknown	5 Milligram, 2/Week	Not Reported

Hydroxychloroquine Sulfate	S	Unknown	40 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S		200 Mg, 2x/Day	Not Reported
Hydroxychloroquine Sulfate	S		40 Mg, 1x/Day	Not Reported
Hydroxychloroquine Sulfate	S		40 Mg, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Ferrous Fumarate/Folic Acid	S		Unk, 1x/Day	Not Reported
Remicade	S		Unk	Not Reported
Naproxen Sodium	S		500 Mg, 2x/Day	Not Reported
Naproxen Sodium	S		1000 Mg, 1x/Day	Not Reported
Naproxen Sodium	S	Oral	500 Mg, 2x/Day	Not Reported
Naproxen Sodium	S	Oral	100 Mg, 2x/Day	Not Reported
Naproxen Sodium	S	Oral	1000 Mg, 1x/Day	Not Reported
Hydroxychloroquine	S		400 Mg, Weekly	Not Reported
Hydroxychloroquine	S		40 Mg, Weekly	Not Reported
Palafer	S		Unk	Not Reported
Pantoprazole Sodium	S		40 Mg, 1x/Day	Not Reported
Celebrex	C	Oral	200 Milligram, Qd	Not Reported
Celebrex	C		Unk	Not Reported
Celebrex	C	Oral	200 Milligram, Qd	Not Reported
Prednisone	C	Unknown	5 Milligram, Qd	Not Reported
Celecoxib	C	Oral	Unk	Not Reported
Celecoxib	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	12197652	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1727368		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported

Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Infection; Inflammation; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Unknown		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Oxycontin	S	Unknown		Not Reported
	Fentanyl	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Gabapentin	S	Oral		Not Reported
	Gabapentin	S	Oral		Not Reported
	Gabapentin	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Omega 3 [Docosahexaenoic Acid;Eicosapentaenoic Acid]	C	Unknown		Not Reported
	Diphenoxylate	C	Unknown	2.5/0.025 Mg Daily	Not Reported
	Actonel	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Aclasta	C	Intravenous (not otherwise specified)		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Nasonex	C	Unknown	2 Sprays Intranasal	Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown	3-4 Times/Day.	Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown	1 Dosage Form	Not Reported
	Ergocalciferol	C	Unknown		Not Reported

	Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
	Loperamide Hydrochloride	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Tylenol	C	Oral	Not Reported
	Tylenol	C	Oral	Not Reported
	Trazodone Hydrochloride	C	Oral	Not Reported
	Perphenazine	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	12511500	EXPEDITED (15-DAY)		OT	CA-ROCHE-1784162			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Arthropathy; Bone Erosion; Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Actemra			S	Unknown			Not Reported
	Crestor			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Gold			S	Unknown			Not Reported

	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rosuvastatin Calcium	S	Unknown	Not Reported
	Rosuvastatin Calcium	S	Oral	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	12919635	EXPEDITED (15-DAY)		OT	CA-ROCHE-1851565		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Actemra			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Kineret			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S	Oral	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Methotrexate	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Cortisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	12946333	EXPEDITED (15-DAY)		OT	CA-ROCHE-1853943		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Methotrexate	S	Parenteral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Other	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Imuran [Azathioprine]	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Etanercept	S	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Prednisone	C		Not Reported
Tofacitinib	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	13112057	EXPEDITED (15-DAY)		OT	CA-ROCHE-1876559		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Subcutaneous	Therapy Duration: 8 Months		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported

Enbrel	S	Subcutaneous	Therapy Duration: 8 Years		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral			Not Reported
Sulfasalazine	S	Oral			Not Reported
Methotrexate	S	Oral	Therapy Duration: 4 Years		Not Reported
Humira	S	Subcutaneous			Not Reported
Arava	S	Unknown	Therapy Duration: 6 Months		Not Reported
Apo-Hydroxyquine	S	Unknown			Not Reported
Apo-Leflunomide	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Leflunomide	S	Unknown			Not Reported
Orencia	S	Subcutaneous			Not Reported
Simponi	S	Subcutaneous			Not Reported
Meloxicam	C	Oral			Not Reported
Xeljanz	C	Oral			Not Reported
Prednisolone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	13178708	EXPEDITED (15-DAY)		OT	CA-ROCHE-1886825			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Contraindicated Product Administered; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache;	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Hereditary Angioedema; Infection; Infection; Intentional Product Use Issue; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Rheumatoid Arthritis; Syncope; Urticaria	Arava	S	Oral	Qd	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown	Qwk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Qmo	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Therapy Duration: 396.0 Nos	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Therapy Duration: 16.0 Years	Not Reported
	Prednisone	C	Unknown		Not Reported
	Prevacid	C	Unknown		Not Reported
	Xeljanz	C	Oral	Therapy Duration: 7.0 Day(S)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	13210355	EXPEDITED (15-DAY)		OT	CA-SA-2015SA178527		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthritis; Condition Aggravated; Drug Ineffective; Hormone	Arava			S		20 Mg, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg,Qd		Sanofi

Level Abnormal; Immobile; Intentional Product Misuse; Loss Of Personal Independence In Daily Activities; Menopausal Symptoms; Menopause; Mobility Decreased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure	Leflunomide	S	Oral	20 Mg, Qd		Sanofi
	Methotrexate	S	Oral	10 Mg, Qw		Not Reported
	Methotrexate	S	Oral	20 Mg, Qw		Not Reported
	Methotrexate	S		Unk		Not Reported
	Methotrexate	S	Oral	20 Mg, Qw		Not Reported
	Methotrexate	S	Oral	10 Mg, Qw		Not Reported
	Methotrexate	S		Unk		Not Reported
	Plaquenil	S	Oral	400 Mg,Qd		Sanofi
	Mefenamic Acid	S	Unknown	400 Mg,Bid		Not Reported
	Mefenamic Acid	S		2 Df, Qd		Not Reported
	Mefenamic Acid	S		2 Df, Qd		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Mg, Qd		Sanofi
	Enbrel	S	Subcutaneous	50 Mg		Not Reported
	Enbrel	S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel	S	Unknown	1 Df		Not Reported
	Enbrel	S		Unk, Qw		Not Reported
	Enbrel	S		50 Unk		Not Reported
	Xeljanz	S	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz	S	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz	S		5 Mg, Bid		Not Reported
	Sulfasalazine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	13229065	EXPEDITED (15-DAY)		OT	CA-ROCHE-1892565		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Joint Swelling;	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	4.0 Months		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Musculoskeletal Disorder; Nasopharyngitis; Neutropenia; Off Label Use; Platelet Count Decreased; Respiratory Tract Infection Viral; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Therapy Duration: 2.0 Year(S)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Xeljanz	S	Oral	Therapy Duration 505.0 Day(S)	Not Reported
	Xeljanz	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown	Therapy Duration: 4.0 Month(S)	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Therapy Duration 2.0 Years	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Advil [Ibuprofen]	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Ketorolac	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	13233820	EXPEDITED (15-DAY)		OT	CA-ROCHE-1893888		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Frustration Tolerance Decreased; Ill-Defined Disorder; Injection Site Bruising; Injection Site	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Nasopharyngitis; Rheumatoid Arthritis; Suicidal Ideation; Treatment Failure; Vein Disorder	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Fosamax	C	Unknown	Not Reported
	Ibuprofen	C	Unknown	Not Reported
	Lisinopril	C	Unknown	Not Reported
	Vitamin D3	C	Unknown	Not Reported
	Fosavance	C		Not Reported
	Synthroid	C	Unknown	Not Reported
	Alendronate Sodium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	13966976	EXPEDITED (15-DAY)		OT	CA-ROCHE-1992036			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug-Induced Liver Injury; Hepatotoxicity; Joint Swelling; Joint Swelling; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In	Actemra			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Therapy Duration: 245.0 Nos		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

Daily Activities; Pain In Extremity; Peripheral Swelling; Therapeutic Response Decreased	Humira	S	Subcutaneous	Solution	Not Reported
	Enbrel	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	14444966	EXPEDITED (15-DAY)		OT	CA-ROCHE-2056327		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Back Pain; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Joint Swelling; Off Label Use; Pain In Extremity; Rheumatoid Arthritis; Treatment Failure; Treatment Failure	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Neoral	S	Subcutaneous	Not Reported
	Neoral	S	Oral	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Arava	C	Oral	Not Reported
	Risedronate	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	14535636	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2018CA0135			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Kineret			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Apo Hydroxyquine			S				Not Reported
	Apo-Mycophenolate			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)	
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S		Not Reported
	Celebrex	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Cellcept	S		Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Methotrexate	C		Not Reported
	Celebrex	C	Unknown	Not Reported
	Humira	C		Not Reported
	Prednisone	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	14539305	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0137			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Kineret			S	Subcutaneous			Not Reported
	Kineret			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S				Not Reported
	Plaquenil			S	Oral			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S		Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Tocilizumab	S	Subcutaneous	Not Reported
	Gold	S	Intramuscular	Not Reported
	Imuran	S		Not Reported
	Leflunomide	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Methotrexate	S		Not Reported
	Methotrexate	C	Oral	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Cortisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	15009839	EXPEDITED (15-DAY)		OT	CA-ROCHE-2137691		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Product Effect Incomplete;	Actemra			S	Unknown	Therapy Duration: 2.0 Years		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 3.0 Years		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Therapeutic Response Decreased; Urinary Tract Infection	Methotrexate	S	Subcutaneous		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Cyclical	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulphate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Desoximetasone	C			Not Reported
	Orencia	C	Unknown	Therapy Duration: 5.0 Years	Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	15065924	EXPEDITED (15-DAY)		DS, OT	CA-BIOVITRUM-2018CA0717		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Disorder; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Kineret			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Unknown			Not Reported

Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Humira	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Methotrexate	S		Not Reported
Actemra	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Oral	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Arava	S	Unknown	Not Reported
Leflunomide	S		Not Reported
Leflunomide	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Rituximab	S		Not Reported
Bupropion	C	Oral	Not Reported
Sulfasalazine	C		Not Reported
Wellbutrin	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	15356144	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2179236		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ilaris			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown	Solution For Injection		Not Reported
	Humira			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S				Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Methotrexate			C	Unknown			Not Reported

	Rituximab			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	15598301	EXPEDITED (15-DAY)		DS, OT	CA-SA-2018SA021997		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg/M2,Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Sulfasalazine			S	Unknown			Not Reported
	Abatacept			S	Unknown	Unk Unk, Unk		Not Reported
	Abatacept			S				Not Reported
	Tocilizumab			S	Unknown	Unk Unk, Unk		Not Reported
	Tocilizumab			S				Not Reported
	Etanercept			S		15 Mg Qwk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	420 Mg, Unk		Not Reported
	Infliximab			S	Unknown	200 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	15781203	EXPEDITED (15-DAY)		OT	CA-SA-2018SA397121			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Leflunomide			S		Unk		Sanofi
	Sulfasalazine			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Sanofi
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil Sulfate			C				Not Reported
	Desoximetasone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	15832234	EXPEDITED (15-DAY)		DS	CA-ROCHE-1893094		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chondropathy; Disability; Drug Ineffective; Headache; Malaise; Sarcoidosis; Tooth Extraction; Tooth Fracture; Weight Increased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Xeljanz	C		Not Reported
	Cephalexin [Cefalexin]	C	Unknown	Not Reported
	Cephalexin Monohydrate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16008854	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016510		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Inflammation; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain;	Diclofenac			S	Unknown			Actavis
	Diclofenac			S	Unknown			Actavis
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Intra-arterial			Barr
	Prednisone			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Paracetamol			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S				Not Reported

Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sinusitis; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S			Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]]	S			Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	2 Gram Daily;	Not Reported
	Sulfasalazine	S	Unknown		Not Reported

Topicort Mild (Desoximetasone)	S	Oral			Not Reported
Topicort Mild (Desoximetasone)	S	Unknown			Not Reported
Apo-Prednisone	S	Unknown			Not Reported
Apo-Prednisone	S				Not Reported
Apo Folic	S	Unknown			Not Reported
Apo Hydroxyquine	S	Unknown	400 Milligram Daily;		Not Reported
Sarilumab	S	Unknown			Not Reported
Stelara	S	Unknown			Not Reported
Sulfathalidine	S	Subcutaneous			Not Reported
Xeljanz	S	Unknown	10 Milligram Daily;		Not Reported
Xeljanz	S				Not Reported
Desoximetasone	S	Oral			Not Reported
Leflunomide	C	Unknown			Not Reported
Atasol	C	Unknown			Not Reported
Salazopyrin	C	Unknown			Not Reported
Tofacitinib Citrate	C	Unknown			Not Reported
Acetaminophen	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16226845	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA110472			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Naproxen			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown			Not Reported
	Actemra			S		Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported

	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Folic Acid	C			Not Reported
	Methotrexate	C		20 Mg	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16231995	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110775			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tocilizumab			S				Not Reported
	Xeljanz			S				Not Reported
	Prednisone			C	Unknown	10 Mg		Not Reported
	Cimzia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16425615	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1061416		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myopathy Toxic	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Teva
	Losartan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16645870	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202595			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Hydroxychloroquine			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S		Solution Intravenous		Not Reported
	Leflunomide			S				Sanofi
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Desoximetasone			C		Not Specified		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16646742	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202696		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Plaquenil			S	Oral			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine			S	Subcutaneous	Unk, Qow		Sanofi
	Enbrel			S	Subcutaneous	Unk Unk, Qw		Not Reported
	Enbrel			S	Subcutaneous	Unk, Duration: 129		Not Reported
	Cimzia			S	Subcutaneous	Unk Unk, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported

Orencia	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Prednisone	C	Oral	10 Mg, Qd		Not Reported
Prednisone	C	Oral	6 Mg, Qd		Not Reported
Prednisone	C	Oral	10 Mg, Qd		Not Reported
Mefenamic Acid	C				Not Reported
Dequalinium Chloride	C				Not Reported
Tylenol [Paracetamol]	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16650735	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202940		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Hydroxychloroquine			S		Unk		Sanofi
	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Minocycline Hydrochloride			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Apo-Azathioprine			S		100 Mg		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S		5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16650736	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202974			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine			S	Oral	400 Mg, Qw		Sanofi
	Hydroxychloroquine			S	Oral	200 Mg, Qow		Sanofi
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Sanofi
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Xeljanz			C				Not Reported
	Folic Acid			C	Oral	5 Mg		Not Reported
	Prednisone			C	Oral			Not Reported
	Tofacitinib Citrate			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16650744	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202752		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Neck Pain	Plaquenil			S				Sanofi
	Methotrexate			S				Not Reported
	Arava			S				Sanofi
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan		S	Intravenous (not otherwise specified)			Not Reported
	Mobicox		C		15 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16651231	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202759		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Hydroxychloroquine Sulfate			S	Unknown	5 Mg, Unk		Sanofi
	Leflunomide			S	Unknown	5 Mg		Sanofi
	Leflunomide			S	Oral	10 Unk		Sanofi
	Methotrexate			S	Unknown	5 Mg, Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Cyclical, Single Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qcy, Cyclical		Not Reported
	Orencia			S	Unknown	750 Mg		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			C	Unknown	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16651242	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA202767		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Site	Plaquenil			S				Sanofi
	Leflunomide			S	Oral			Sanofi
	Methotrexate			S	Subcutaneous	15 Mg/M2, Qw		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg/M2		Not Reported
	Sulfasalazine			S				Not Reported
	Rituximab			S	Intravenous (not	420 Mg		Not Reported

Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Decreased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Rituximab	S	otherwise specified)	Unk	Not Reported
	Tocilizumab	S			Not Reported
	Tocilizumab	S			Not Reported
	Orencia	S			Not Reported
	Orencia	S			Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	200 Mg, Qw	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	200 Mg, Qm	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qw	Not Reported
	Adalimumab	S	Subcutaneous	40 Mg, Qw	Not Reported
	Adalimumab	S		Unk	Not Reported
	Actemra	S			Not Reported
	Enbrel	S			Not Reported
	Enbrel	S	Subcutaneous	15 Mg, Qw	Not Reported
	Etanercept	S		15 Mg, Qw	Not Reported
	Etanercept	S	Subcutaneous	15 Mg, Qw	Not Reported
	Abatacept	S			Not Reported
	Abatacept	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16651276	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202864			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	600 Mg, Qd [1 Every 1 Day(S)]		Sanofi
	Hydroxychloroquine			S	Oral	20 Mg, Qd		Sanofi
	Arava			S	Oral	20 Mg, Qd [1 Every 1 Day(S)]		Sanofi
	Methotrexate			S	Oral	10 Mg, Qw [1 Every 1 Week(S)]		Not Reported

Actemra	S				Not Reported
Enbrel	S	Subcutaneous			Not Reported
Folic Acid	C	Unknown	1 Df, Qw [1 Every 1 Week(S)]		Not Reported
Prednisone	C				Not Reported
Simponi	C	Subcutaneous	Formulation: Solution		Not Reported
Xeljanz	C	Oral	5 Mg, Qd [2 Every 1 Day(S)]		Not Reported
Xeljanz	C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16655167	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202673			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis	Hydroxychloroquine			S	Unknown	2 Df, Bid,200 Mg		Sanofi
	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	25 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Unknown	200 Mg, Biw, Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown	25 Mg, Biw		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Tocilizumab			S	Unknown	Unk Unk, Unk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk Unk, Unk, Solution Intramuscular		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Qm		Not Reported
	Xeljanz			S	Unknown	Unk Unk, Unk		Not Reported
	Desoximetasone			C	Unknown	Unk Unk, Unk		Not Reported
	Darifenacin Hydrobromide			C	Unknown	Unk Unk, Unk		Not Reported
	Darifenacin			C	Unknown	Unk Unk, Unk		Not Reported

Ativan	C	Unknown	Unk Unk, Unk	Not Reported
Codeine	C	Unknown	Unk Unk, Unk	Not Reported
Anakinra	C	Unknown	Unk Unk, Unk	Not Reported
Dexamethasone	C	Unknown	Unk Unk, Unk	Not Reported
Dilaudid	C	Unknown	Unk Unk, Unk	Not Reported
Diphenhydramine	C	Unknown	Unk Unk, Unk	Not Reported
Furosemide	C	Unknown	Unk Unk, Unk	Not Reported
Hydromorphone	C	Unknown	Unk Unk, Unk	Not Reported
Kenalog [Triamcinolone Acetonide]	C	Unknown	Unk Unk, Unk,Suspension Intra-Articular	Not Reported
Loperamide	C	Unknown	Unk Unk, Unk	Not Reported
Morphine Sulphate	C	Unknown	Unk Unk, Unk	Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown	Unk Unk, Unk	Not Reported
Omnaris	C	Unknown	Unk Unk, Unk, Spray Metered Dose	Not Reported
Oxyneo	C	Unknown	Unk Unk, Unk,Tablet-Extended Release	Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Unk Unk, Unk Tablet Enteric Coated	Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown	Unk Unk, Unk	Not Reported
Restasis	C	Unknown	Unk Unk, Unk, Emulsion	Not Reported
Synthroid	C	Unknown	Unk Unk, Unk	Not Reported
Trimethoprim	C	Unknown	Unk Unk, Unk	Not Reported
Urispas	C	Unknown	Unk Unk, Unk	Not Reported
Vagifem	C	Unknown	Unk Unk, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16655179	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202618		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi

Alopecia; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure	Hydroxychloroquine Sulfate	S	Oral	Unk	Sanofi
	Plaquenil	S		400 Mg, Qd	Sanofi
	Folic Acid	S		Unk	Not Reported
	Folic Acid	S		5 Mg	Not Reported
	Folic Acid	S		1 Mg	Not Reported
	Prednisone	S		Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Prednisone	S		Unk	Not Reported
	Cetirizine Hydrochloride	S		10 Mg	Not Reported
	Cetirizine Hydrochloride	S		Unk	Not Reported
	Methotrexate	S		20 Mg, Qd	Not Reported
	Methotrexate	S	Oral	25 Mg	Not Reported
	Pseudoephedrine Hydrochloride	S		Unk	Sanofi
	Arava	S	Oral	Unk	Sanofi
	Arava	S		Unk	Sanofi
	Cortisone Acetate	S		25 Mg	Not Reported
	Alendronate Sodium	S		Unk	Not Reported
	Sulfasalazine	S		500 Mg	Not Reported
	Sulfasalazine	S	Oral	1000 Mg, Bid	Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S		Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not	Unk	Not Reported

			otherwise specified)		
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfathalidine	S		Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Golimumab	S		Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Salazopyrin	C		Unk	Not Reported
	Diclofenac	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16656983	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA202972		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthritis; Condition Aggravated; Drug Ineffective; Hormone Level Abnormal; Immobile; Intentional Product Misuse; Loss Of Personal Independence In Daily Activities; Menopausal Symptoms; Menopause; Mobility Decreased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine			S	Oral	1 Df, Qd		Sanofi
	Plaquenil			S	Oral	1 Df, Qd		Sanofi
	Leflunomide			S	Oral	1 Df, Qd		Sanofi
	Leflunomide			S	Oral	1 Mg, Qd		Sanofi
	Arava			S		1 Df, Qd		Sanofi
	Mefenamic Acid			S		2 Df, Qd		Not Reported
	Mefenamic Acid			S		2 Df, Qd		Not Reported
	Mefenamic Acid			S		2 Df, Qd		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Methotrexate			S		Unk		Not Reported

Enbrel	S	Subcutaneous	50 Mg		Not Reported
Enbrel	S		Unk		Not Reported
Enbrel	S		Unk Unk, Qw		Not Reported
Enbrel	S		1 Df		Not Reported
Enbrel	S		50 Mg		Not Reported
Xeljanz	S	Oral	2 Df, Qd (5 Mg Stength)		Not Reported
Xeljanz	S		Unk		Not Reported
Xeljanz	S		2 Df, Qd		Not Reported
Xeljanz	S		2 Df, Qd (5 Mg Stength)		Not Reported
Sulfasalazine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16686491	EXPEDITED (15-DAY)		OT	CA-SA-2019SA209083			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Arava			S	Oral	20 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Oral	600 Mg, Qw		Sanofi
	Hydroxychloroquine			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Folic Acid			C	Unknown	1 Df, Qw		Not Reported
	Prednisone			C	Unknown	Unk Unk, Unk		Not Reported
	Simponi			C	Unknown	Unk Unk, Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Xeljanz			C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16710769	EXPEDITED (15-DAY)		OT	DE-ASTRAZENECA-2019SF17234			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Omeprazole			S	Oral			Not Reported
	Omeprazole			S	Oral			Not Reported
	Ramipril			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Not Reported
	Ramipril			S	Oral			Not Reported
	Volibris			S	Unknown			Not Reported
	Volibris			S	Unknown			Not Reported
	Volibris			S	Unknown			Not Reported
	Volibris			S	Unknown			Not Reported
	Volibris			S	Oral			Not Reported
	Volibris			S	Oral			Not Reported
	Eliquis			S	Unknown			Not Reported
	Eliquis			S	Unknown			Not Reported
	Quensyl			S	Unknown			Not Reported
	Quensyl			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Sildenafil Citrate			S	Unknown			Not Reported
	Roactemra			S	Subcutaneous			Not Reported
	Roactemra			S	Subcutaneous			Not Reported
	Spasmolyt			S	Unknown			Not Reported
	Spasmolyt			S	Unknown			Not Reported
	Spasmolyt			S	Unknown			Not Reported
	Spasmolyt			S	Unknown			Not Reported
	Pregabalin			S	Unknown			Not Reported
	Pregabalin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16822887	EXPEDITED (15-DAY)		HO, OT	BR-GLAXOSMITHKLINE-BR2019GSK067189		25 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Dermatitis; Headache; Herpes Zoster; Inappropriate Schedule Of Product Administration; Leukocytosis; Product Availability Issue; Product Dose Omission; Pyrexia; Rash; Skin Injury; Skin Lesion; Systemic Lupus Erythematosus; Urinary Tract Infection; Weight Decreased	Belimumab			S		Unk		Glaxosmithkline
	Belimumab			S		Unk		Glaxosmithkline
	Belimumab			S		630 Mg, Unk		Glaxosmithkline
	Mycophenolate Sodium			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	16939747	EXPEDITED (15-DAY)		OT	CA-ROCHE-2436179		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17037780	EXPEDITED (15-DAY)		LT	CA-ROCHE-2461506			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Prescribed Underdose; Product Use In Unapproved Indication; Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non-	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	5.0 Month(S)		Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Triamcinolone			S	Intra-articular			Not Reported
	Triamcinolone			S				Not Reported
	Enbrel			S	Subcutaneous	7.0 Month(S)		Not Reported
	Humira			S	Subcutaneous	2.0 Month(S)		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	4.0 Month(S)		Not Reported
	Kineret			S	Subcutaneous	1.0 Year(S)		Not Reported
	Kineret			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

Responder; Vomiting; Wheelchair User	Methotrexate Sodium		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)	2.0 Month(S)	Not Reported
	Orencia		S	Unknown		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Actemra		S	Unknown		Not Reported
	Actemra		S			Not Reported
	Hydroxychloroquine Sulfate		S	Oral		Not Reported
	Anakinra		S	Subcutaneous		Not Reported
	Anakinra		S	Unknown		Not Reported
	Folic Acid		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17132363	EXPEDITED (15-DAY)		OT	CA-ROCHE-2489219			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported

	Hydroxychloroquine	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Amoxicillin	C	Unknown	Not Reported
	Amoxicillin Trihydrate;Clavulanate Potassium	C	Unknown	Not Reported
	Amoxil [Amoxicillin]	C	Unknown	Not Reported
	Bcg Vaccine	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17134891	EXPEDITED (15-DAY)		LT	CA-ROCHE-2485918		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported

Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S		Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Marijuana	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Minocycline	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Oxycodone	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Xeljanz	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported

	Sodium Aurothiomalate	S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Cannabis Sativa	S	Unknown		Not Reported
	Kineret	C	Unknown		Not Reported
	Lyrica	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17154597	EXPEDITED (15-DAY)		OT	CA-ROCHE-2456781		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gingival Bleeding; Headache; Liver Function Test Increased; Syncope	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Prednisone			C				Not Reported
	Prevacid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17233345	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508677		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Tremor	Actemra	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown	10 Mg, 15 Mg	Not Reported
	Remicade	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Pantoprazole Magnesium	C	Unknown		Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Zopiclone	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17250077	EXPEDITED (15-DAY)		OT	CA-ROCHE-2517539			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Off Label Use; Oral	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported

Discomfort; Rheumatoid Arthritis; Treatment Failure	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Kevzara	S	Unknown	Not Reported
	Rabeprazole Sodium	C	Oral	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17265226	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516327		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

	Etanercept	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methylprednisolone	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17310198	EXPEDITED (15-DAY)		OT	CA-ROCHE-2528070		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Dermatitis Allergic; Investigation Abnormal; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Septra			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17349762	EXPEDITED (15-DAY)		OT	CA-ROCHE-2532663			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Condition Aggravated; Contraindicated Product Administered; Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Impaired Gastric Emptying; Influenza; Off Label Use; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17364086	EXPEDITED (15-DAY)		LT	CA-ROCHE-2537110			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported

Anakinra	S	Unknown	Not Reported
Anakinra	S		Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S		Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S		Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S		Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S		Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Methotrexate	S		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S		Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S		Not Reported
Ilaris	S	Subcutaneous	Not Reported
Ilaris	S		Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17391683	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536704			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

Intolerance; Hypersensitivity; Rash			otherwise specified)	
	Rituxan	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Acetylsalicylic Acid	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S		Not Reported
	Gabapentin	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17654444	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-017303		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Abnormal; Breast Cancer Metastatic; Burning Sensation; Constipation; Dementia Alzheimer'S Type; Expired Product Administered; Gait Disturbance; Intentional Product Misuse; Malaise; Off Label Use; Paronychia; Skin Plaque; Systemic Lupus Erythematosus; Toe Amputation	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo
	Amoxicillin+Clavulanic Acid			S				Aurobindo
	Amoxicillin+Clavulanic Acid			S				Aurobindo
	Plaquenil			S	Unknown	3 Dosage Form		Not Reported
	Plaquenil			S	Unknown	2 Dosage Form, Two Times A Day (One In Morning And One In Evening)		Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17668617	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202003002364			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alkalosis; Alkalosis; Atrial Flutter; Deep Vein Thrombosis; Drug Level Increased; Enterococcal Infection; Haematuria; Haemoglobin Decreased; Hyperglycaemia; Hypoxia; Off Label Use; Pneumonia Bacterial; Quadriparesis; Staphylococcal Infection; Vascular Device Infection	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		600 Mg, Qd Film-Coated Tablet		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		600mg In The Morning, 400mg In The Evening Film-Coated Tablet		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		400 Mg, Qd Film-Coated Tablet		Concordia
	Lovenox			S	Subcutaneous	0.6 Ml, Bid (Q12h)		Not Reported
	Lovenox			S	Subcutaneous	0.7 Ml, Qd		Not Reported
	Lovenox			S	Subcutaneous	1.4 Ml, Qd		Not Reported
	Paracetamol			S		4 G, Qd		Not Reported
	Paracetamol			S				Not Reported
	Movicol			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Lasilix			C		Unk		Not Reported
	Lantus			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Pantoprazole			C				Not Reported
	Tienam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17673548	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2020-017887		74 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Levofloxacine Arrow Film-Coated Tablets 500mg			S	Oral	2 Dosage Form, Once A Day		Aurobindo
	Sandoz Amoxi Clav			S	Oral	3 Dosage Form, Once A Day		Not Reported
	Lovenox			S	Subcutaneous	1 Dosage Form, Once A Day		Not Reported
	Primperan			S	Oral	1 Dosage Form		Not Reported

Ritonavir Mylan	S	Oral	1 Dosage Form, Once A Day		Not Reported
Azithromycine Sandoz [Azithromycin]	S	Oral	4 Dosage Form, Once A Day		Not Reported
Doliprane	S	Oral	1 Dosage Form		Not Reported
Plaquenil	S	Oral	3 Dosage Form, Once A Day		Not Reported
Darunavir Mylan	S	Oral	1 Dosage Form, Once A Day		Not Reported
Ceftriaxone	S	Intravenous (not otherwise specified)	1 Dosage Form, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17678836	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2020-017962		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged	Levofloxacine Arrow Film-Coated Tablets 500mg			S	Oral	1000 Milligram, Once A Day		Aurobindo
	Levofloxacine Arrow Film-Coated Tablets 500mg			S	Oral	500 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17730463	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589860			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Hydroxychloroquine			S	Unknown				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Orencia			S	Intravenous (not otherwise specified)				Not Reported
	Prednisone			S	Intravenous (not otherwise specified)				Not Reported
	Prednisone			S	Intravenous (not otherwise specified)				Not Reported
	Prednisone			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17732452	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590075		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Off Label Use; Pneumonia; Product Use In Unapproved Indication;	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	190.0 Days		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Otezla	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Not Reported
	Calcium	C	Unknown	Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Estradiol	C	Unknown	Not Reported
	Estrogel	C	Unknown	Not Reported
	Estrogel	C	Unknown	Not Reported
	Furosemide	C	Unknown	Not Reported
	Morphine	C	Unknown	Not Reported
	Potassium Chloride	C	Unknown	Not Reported
	Valsartan	C	Unknown	Not Reported
	Xalatan	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Zingiber Officinale	C	Oral	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Baclofen	C	Unknown	Not Reported
	Tofacitinib Citrate	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17749115	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592718			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17751944	EXPEDITED (15-DAY)		OT	CA-ROCHE-1710933		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17752813	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1045214		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis; Off Label Use	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Dolquine			S	Other	400 Mg Dia		Mylan
	Dolquine			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17752858	EXPEDITED (15-DAY)		DE	ES-MYLANLABS-2020M1045229		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Drug Interaction; Off Label Use; Tachyarrhythmia	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Hidroxicloroquina Sulfato			S	Oral	200 Milligram, Qd		Mylan
	Ceftriaxona /00672201/			C	Intravenous (not otherwise specified)	1 Gram, Qd		Mylan
	Tocilizumab			C	Intravenous (not otherwise specified)	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17754839	EXPEDITED (15-DAY)		OT	CA-ROCHE-1674787		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Kineret			S	Subcutaneous	100mg Per Syringe Singleuse, Preservativefree Prefilled Syringes		Not Reported

Enbrel	S	Subcutaneous	Therapy Duration: 107 Days	Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Imuran [Azathioprine]	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Apo-Leflunomide	S	Intravenous (not otherwise specified)		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Azathioprine	S	Intravenous (not otherwise specified)		Not Reported
Azathioprine	S	Unknown		Not Reported
Methotrexate	S	Intravenous (not otherwise specified)		Not Reported
Methotrexate	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Anakinra	S	Subcutaneous		Not Reported
Anakinra	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Etanercept	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Orencia	S	Unknown		Not Reported

	Sulfasalazine	C	Unknown	Not Reported
	Wellbutrin	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17757977	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20200500983			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abscess; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatic Fibrosis; Interstitial Lung Disease; Joint Swelling; Rheumatoid Arthritis; Sepsis; Spinal Cord Infection	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S				Not Reported
	Azathioprine			S				Not Reported
	Diclofenac			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Mobicox			S				Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Naproxen			S				Not Reported
	Sulfasalazine			S				Not Reported
	Vioxx			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			C	Intramuscular			Not Reported
	Plaquenil /00072602/			C				Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17757978	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200500977		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered;	Remicade			S	Intravenous (not otherwise specified)			Janssen

Drug Ineffective; Drug Intolerance; Inflammation; Joint Stiffness; Joint Swelling; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Prednisone	C		Not Reported
	Sulfasalazine	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17757979	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200500971		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Blood Glucose Abnormal; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Secretion Discharge; Sputum Discoloured; Thrombosis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported

	Warfarin Sodium	S	Unknown	Not Reported
	Warfarin Sodium	S	Unknown	Not Reported
	Amitriptyline	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17757980	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200500974		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Crohn'S Disease; Drug Ineffective; Elbow Operation; Inappropriate Schedule Of Product Administration; Neck Pain; Off Label Use; Pain In Extremity; Product Dose Omission; Therapeutic Product Effect Decreased	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S				Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17758008	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200500964		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported

Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17758010	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200500966			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Bupropion			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported

	Wellbutrin	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17758054	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437417		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17758059	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437409		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Drug Resistance; Hip Arthroplasty; Pulmonary Oedema; Rheumatoid	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Apo-Hydroxyquine			S	Unknown			Not Reported

Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituximab Gp2013	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Actemra	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17764530	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596720		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17765745	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200500989			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Gold			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17765811	EXPEDITED (15-DAY)		HO	CA-ROCHE-2591759			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Back Injury; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Liver Function Test Increased; Nausea; Product Label Confusion; Rheumatoid Arthritis;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine Sodium			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Etanercept	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17771016	EXPEDITED (15-DAY)		LT	FR-MYLANLABS-2020M1045647		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Sinus Bradycardia	Levofloxacin			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Plaquenil /00072603/			S	Oral	600 Milligram, Qd		Mylan
	Zithromax			S	Oral	500 Milligram, Qd		Mylan
	Zyvoxid			C	Intravenous (not otherwise specified)	1200 Milligram		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17782453	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020161893		61 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Covid-19; Diarrhoea; Febrile Neutropenia; Fusobacterium Infection; Mucosal Inflammation;	Methylprednisolone Sodium Succinate			S	Intravenous (not otherwise specified)	125 Mg		Pfizer
	Carboplatin			S	Other	750 Unk, Daily(1/3 Weeks)		Pfizer

Nausea	Carboplatin	S	Other	750 Unk, Daily(1/3 Weeks)	Pfizer
	Carboplatin	S	Other	600 Unk, Daily(1/3 Weeks)	Pfizer
	Etoposide	S	Unknown	213 Unk(Day 1,2,3 3 Weeks)	Not Reported
	Etoposide	S	Unknown	213 Unk(Day 1,2,3 3 Weeks)	Not Reported
	Etoposide	S		165 Unk(Day 1,2,3 3 Weeks)	Not Reported
	Nivolumab	S	Unknown	360, 1/3 Weeks	Not Reported
	Nivolumab	S		360, 1/3 Weeks	Not Reported
	Nivolumab	S	Unknown	360, 1/3 Weeks	Not Reported
	Hydroxychloroquine	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Clavulanate Potassium	C	Unknown	Unk	Not Reported
	Clavulanate Potassium	C	Unknown	Unk	Not Reported
	Clavulanate Potassium	C	Unknown	Unk	Not Reported
	Piperacillin Sodium	C	Unknown	Unk	Not Reported
	Ciprofloxacin	C	Unknown	Unk	Not Reported
	Ciprofloxacin	C	Unknown	Unk	Not Reported
	Amoxicillin	C	Other	Unk	Not Reported
	Amoxicillin	C	Other	Unk	Not Reported
	Amoxicillin	C	Other	Unk	Not Reported
	Tazocel	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Ceftriaxone	C	Unknown	Unk	Not Reported
	Metronidazole	C	Unknown	Unk	Not Reported
	Cefepime	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Tazobactam	C		Unk	Not Reported
	Oxygen	C	Unknown	Unk	Not Reported
	Quetiapine	C		50 Mg	Not Reported

	Buscapina	C	30 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17800342	EXPEDITED (15-DAY)		DE, HO, OT	US-ADVANZ PHARMA-202005005269			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported
	Tacrolimus			C		Unk		Not Reported
	Mycophenolate Mofetil			C		Unk		Not Reported
	Prednisone			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17801059	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597847			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17801162	EXPEDITED (15-DAY)		OT	CA-SA-2020SA122504			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Demerol			S	Unknown			Sanofi
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Bisoprolol Salt Not Specified			S	Unknown			Not Reported
	Pethidine Hydrochloride			S	Unknown			Sanofi
	Erythromycin			S	Unknown			Sanofi
	Erythromycin			S	Unknown			Sanofi
	Erythromycin			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Metronidazole			S	Unknown			Sanofi
	Norfloxacin			S	Unknown			Not Reported
	Plaquenil			S	Oral	400 Mg		Sanofi
	Levofloxacin			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Arthrotec			S	Intracardiac			Not Reported
	Ceclor			S	Unknown			Not Reported
	Celebrex			S	Oral	200 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	400 Mg		Not Reported
	Lyrica			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17801165	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL		57 YR	Female	ESP

INDUSTRIES LTD-
2020RR-247402

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia ()		Sun
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg ; In Total		Not Reported
	Lopinavir/Ritonavir			S	Oral	2u Cada 12h ()		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Mg Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17801207	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201806-001951			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthrodesis; Fatigue; Gait Disturbance	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Meloxicam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17801367	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202005005477			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17801415	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602160			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Product Use Issue;	Actemra			S	Unknown			Not Reported

Rheumatoid Arthritis	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Bupropion	C	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Wellbutrin	C	Unknown	Tablet (Extendedrelease)	Not Reported
	Wellbutrin	C	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17801454	EXPEDITED (15-DAY)		DE, HO, OT	US-ADVANZ PHARMA-202005005382			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Product Use In	Hydroxychloroquine			S		Unk		Concordia

Unapproved Indication	Azithromycin	S	Unk	Not Reported
	Sirolimus	C	Unk	Not Reported
	Prednisone	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17801559	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598903		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

Prednisone	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous drip	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17801562	EXPEDITED (15-DAY)		HO	FR-CADILA HEALTHCARE LIMITED-FR-ZYDUS-050881			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Purpura; Thrombocytopenia	Azithromycin			S	Oral	Unk		Zydus Pharm
	Cefotaxime			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported
	Loxen [Loxoprofen Sodium]			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Noradrenaline [Norepinephrine]			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Lovenox [Levofloxacin]			S	Subcutaneous	Unk		Not Reported
	Inexium [Esomeprazole Sodium]			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sufentanil			C				Not Reported
	Nimbex			C				Not Reported
	Hypnovel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17801662	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA202968		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; C-Reactive Protein Increased; Condition Aggravated; Disability; Eye Disorder; Joint Swelling; Mobility Decreased; Musculoskeletal Pain; Ocular Toxicity; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased	Plaquenil			S	Unknown			Sanofi
	Hydroxychloroquine			S	Unknown	400mg, Qd: 1 Every 1 Day (S)		Sanofi
	Leflunomide			S	Unknown	20mg, Qd: 1 Every 1 Days (S)		Sanofi
	Methotrexate			S	Oral	20mg, Qw: 1 Every 1 Week(S)		Not Reported
	Arava			S	Unknown			Sanofi
	Orencia			S	Unknown	125mg, Qw: 1 Every 1 Week(S)		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw; 1 Every 1 Week(S)		Not Reported
	Humira			S	Subcutaneous	40mg, Qow : 1 Every 2 Week(S)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17801713	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598629			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Leflunomide			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported

	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802035	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3408590-00		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Gastrointestinal Pain	Kaletra 200/50			S	Oral			Not Reported
	Hidroxicloroquina			S	Oral			Not Reported
	Omeprazol			C	Oral			Not Reported
	Paracetamol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802249	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235824			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazol			S	Unknown			Not Reported
	Prednisone			S	Intravenous (not			Not Reported

					otherwise specified)					
	Remicade			S	Intravenous (not otherwise specified)					Not Reported
	Rituximab			S	Intravenous (not otherwise specified)					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802251	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236229			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802291	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020020250		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Arthropathy; Blood Glucose Increased; Blood Pressure Diastolic Abnormal; Blood Pressure Diastolic Decreased; Blood Pressure Diastolic Increased; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Increased; Bronchitis; Cardiac Disorder; Contusion; Croup Infectious; Drug Ineffective; Fatigue; Fibromyalgia; Foot Deformity; Gastroenteritis Viral; Headache; Heart Rate Increased; Hypersensitivity; Hypertension; Hypotension; Immunosuppression; Influenza; Infusion Related Reaction; Insomnia; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Oropharyngeal Pain; Pain; Pain In Extremity; Pertussis; Productive Cough; Rash; Stress; Therapeutic Response Decreased; Treatment Failure; Weight Decreased; Weight Increased	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, Monthly (Qm)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	800 Milligram, Monthly (Qm)		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S		20 Milligram, Weekly (Qw)		Not Reported
	Rosuvastatin Calcium			S				Not Reported
	Sulfasalazine			S				Not Reported
	Folic Acid			C				Not Reported
	Humalog			C				Not Reported
	Sertraline Hydrochloride			C				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802319	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598683			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Prefilled Syringe.		Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine			S	Unknown			Not Reported

	Hydrochloride]				
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802457	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236226			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate Sodium			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazol			S	Unknown			Not Reported
	Plaquenil[Hydroxychloroquine			S	Unknown			Not Reported

	Sulfate]			
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802571	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600294			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cortisone Acetate			C	Subcutaneous			Not Reported
	Desoximetasone			C	Oral			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802668	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600829			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802709	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1235783		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage; Vessel Puncture Site Haemorrhage	Hidroxicloroquina (2143a)			S	Oral	400 Mg		Teva
	Enoxaparina (2482a)			S	Subcutaneous	40 Mg		Not Reported
	Dexametasona (722a)			S	Intravenous (not otherwise specified)	20 Milligram Daily;		Not Reported
	Acetilsalicilato De Lisina			S	Intravenous (not otherwise specified)	200 Mg		Not Reported
	Adiro 100 Mg Comprimidos Gastrorresistentes Efg , 500 Comprimidos			S	Oral	100 Milligram Daily; Cp		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802725	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601899		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Rituximab			S	Intravenous drip			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802778	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236801		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Unknown			Actavis
	Prednisolone			S	Unknown			Actavis
	Risedronate Sodium			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Plaquenil	S	Unknown			Not Reported
Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Oral			Not Reported
Cyclobenzaprine	C	Unknown			Not Reported
Desoximetasone	C	Unknown	5 Milligram Daily;		Not Reported
Desoximetasone	C	Unknown			Not Reported
Leflunomide	C	Unknown			Not Reported
Prednisone Acetate	C	Unknown	5 Milligram Daily;		Not Reported
Tylenol/00020001/	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802781	EXPEDITED (15-DAY)		HO	ES-ACCORD-182405		49 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gr Day		Not Reported
	Azithromycin			S	Oral	500 Mg Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802784	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600492		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Musculoskeletal Stiffness	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	3.0 Years		Not Reported
	Sulfasalazine			S	Unknown	3.0 Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802794	EXPEDITED (15-DAY)		HO, OT	ES-ACCORD-182375		56 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hypoacusis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Azithromycin			S	Oral	500 Mg Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802827	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597599		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Osteoporotic Fracture; Spinal Compression Fracture	Actemra			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol			C	Unknown	Tablet (Extended Release)		Not Reported
	Xeljanz			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802925	EXPEDITED (15-DAY)		OT	CA-ROCHE-1956506		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Ineffective; Drug Intolerance; Eye Disorder;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported

Fatigue; Pulmonary Mass; Rheumatoid Nodule; Weight Decreased	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802931	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600444		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Off Label Use; Oral Discomfort; Treatment Failure; Uveitis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Kevzara			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Rabeprazole Sodium	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802958	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236215			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802965	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236061			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo Prednison			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Topicort [Hydrocortisone Acetate]			S	Topical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803035	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202005005562			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803036	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202005005560			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803037	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202005005561			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803109	EXPEDITED (15-DAY)		HO, OT	ES-ACCORD-182473		48 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Colchicine			S	Oral	0.5 Mg Every 12 H		Not Reported
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803135	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236219		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803232	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20200503708		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity	Otezla			S	Oral			Celgene
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	2 Dosage Forms		Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803307	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202005005559			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803317	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1235961		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidrocortisona (54a)			S	Intravenous (not otherwise specified)	200 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803361	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1237155		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Prednisone	S	Unknown		Actavis
	Tocilizumab	S	Unknown		Not Reported
	Sulfathalidine	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	2000 Milligram Daily;	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram Daily;	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Oral	25 Milligram Daily;	Not Reported
	Methotrexate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Fosamax	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported

	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Diclofenac	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803365	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598528		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Synovitis; Terminal State; Thrombosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S				Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803486	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1045225		47 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Off Label Use	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Azithromycin			S				Not Reported
	Dolquine			S	Oral	400 Mg Dia		Mylan
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	2 Gr Dia		Mylan
	Ceftriaxona /00672201/			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803596	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005298			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803597	EXPEDITED (15-DAY)		DE, HO, OT	US-ADVANZ PHARMA-202005005393			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Cardiac Arrest; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported
	Mycophenolate Mofetil			C		Unk		Not Reported
	Prednisone			C		High Dose		Not Reported
	Levofloxacin			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803605	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-16827		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Rheumatoid Arthritis; Synovitis	Brenzys			S	Unknown	Unknown		Not Reported
	Methotrexate Sodium			S	Oral	15 To 20 Mg (More Than Three Months)		Not Reported
	Hydroxychloroquine			S	Unknown	200 To 400 Mg (More Than Three Months)		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803681	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2595853		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown				Not Reported
	Remicade			S	Unknown				Not Reported
	Simponi			S	Subcutaneous				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Xeljanz			S	Unknown				Not Reported
	Xeljanz			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803729	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597677			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Off Label Use	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803798	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597892			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803809	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1048495		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Purpura; Thrombocytopenia	Cefotaxime			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Azithromycin			S	Oral	Unk		Not Reported
	Norepinephrine			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Inexium /01479302/			S	Intravenous (not otherwise specified)	Unk		Mylan
	Lovenox			S	Subcutaneous	Unk		Mylan
	Plaquenil /00072603/			S	Oral	Unk		Mylan
	Loxen /00639802/			S	Intravenous (not otherwise specified)	Unk		Mylan
	Sufentanil			C		Unk		Mylan
	Nimbex /01302502/			C		Unk		Mylan
	Hypnovel /00634101/			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803845	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598105		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Actemra		S	Unknown	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Risedronate Sodium		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803855	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235944			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Tofacitinib Citrate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803880	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598433		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Laboratory Test Abnormal	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17803997	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235976			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Drug Intolerance; Foot Deformity; Inguinal Hernia;	Prednisone			S	Unknown	15 Milligram Daily;		Actavis
	Calcium Carbonate			S	Oral	3 Dosage Forms Daily;		Not Reported

Interstitial Lung Disease; Joint Dislocation; Periarticular Disorder; Post-Traumatic Neck Syndrome; Rheumatoid Arthritis	Methotrexate	S	Unknown		Barr
	Celebrex	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Relafen	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	3000 Milligram Daily;	Not Reported
	Magnesium Aspartate	C	Oral	3 Dosage Forms Daily;	Not Reported
	Omega 3 [Fish Oil]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17804016	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236175			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Lupus-Like Syndrome; Swelling Face	Methotrexate			S	Unknown			Barr
	Mycophenolate Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17804088	EXPEDITED (15-DAY)		HO	ES-GLAXOSMITHKLINE-ES2020079133		83 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hyponatraemia	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gr		Glaxosmithkline
	Salbutamol			S	Respiratory (inhalation)	2-2-2 Inh		Glaxosmithkline

	Symbicort Turbuhaler		S	Respiratory (inhalation)	2-2-2	Not Reported
	Azithromycin		S	Oral	500 Mg Day	Not Reported
	Hydroxychloroquine		S	Oral	400 Mg Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17804295	EXPEDITED (15-DAY)		HO	CA-ROCHE-2598537		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Pollakiuria; Product Dose Omission	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leucovorin [Folinic Acid]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17804335	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1048553		49 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Qd, 500 Mg Dia		Not Reported
	Azithromycin			S				Not Reported
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	2 Gram, Qd, 2 Gr Dia		Mylan
	Ceftriaxona /00672201/			S				Mylan
	Hidroxicloroquina /00072601/			S	Oral	400 Milligram, Qd, 400 Mg Dia		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17804502	EXPEDITED (15-DAY)		DS, HO, OT	CA-CELGENEUS-CAN-20200503932		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Disorder; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red	Otezla			S	Oral			Celgene
	Otezla			S	Oral	120 Milligram		Celgene
	Otezla			S				Celgene
	Actemra			S	Unknown	680 Milligram		Not Reported
	Actemra			S	Unknown	360 Milligram		Not Reported
	Actemra			S	Unknown	2.68 Milligram		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Alendronate Sodium			S	Unknown	70 Milligram		Not Reported
	Alendronate Sodium			S	Unknown	70 Milligram		Not Reported
	Alendronic Acid			S	Unknown	70 Milligram		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Ibuprofen			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral	500 Milligram		Not Reported
	Apo-Leflunomide			S	Oral	380 Milligram		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram		Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Cyclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	20 Milligram		Not Reported

Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Tongue Disorder; Ulcer	Hydroxychloroquine	S	Oral	200 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Ibuprofen	S	Oral	600 Milligram	Not Reported
	Ibuprofen	S	Oral	600 Milligram	Not Reported
	Infliximab	S	Oral		Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Methotrexate	S	Oral	12 Milligram	Not Reported
	Methotrexate	S	Oral	10 Milligram	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Oral	10 Milligram	Not Reported
	Methotrexate	S	Oral	10 Milligram	Not Reported
	Methotrexate	S	Oral	10 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram	Not Reported
	Methotrexate	S	Unknown	17.5 Milligram	Not Reported
	Methotrexate	S	Unknown	15 Milligram	Not Reported
	Methotrexate	S	Unknown	12 Milligram	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram	Not Reported
	Methotrexate	S	Unknown	10 Milligram	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram	Not Reported
	Methotrexate	S	Unknown	12 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram	Not Reported
	Mogadon	S	Oral	5 Milligram	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram	Not Reported

Myochrysine	S	Intramuscular	50 Milligram	Not Reported
Myochrysine	S	Intramuscular	25 Milligram	Not Reported
Orencia	S	Intravenous drip	760 Milligram	Not Reported
Orencia	S	Unknown	780 Milligram	Not Reported
Orencia	S	Subcutaneous		Not Reported
Remicade	S	Intravenous drip		Not Reported
Rituxan	S	Unknown	2000 Milligram	Not Reported
Rituximab	S	Intravenous drip	2000 Milligram	Not Reported
Simponi	S	Subcutaneous		Not Reported
Stelara	S	Subcutaneous		Not Reported
Sulfasalazine	S	Endocervical	500 Milligram	Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Diphenhydramine Hcl	C	Unknown		Not Reported
Colchicine	C	Oral		Not Reported
Dexilant	C	Oral		Not Reported
Febuxostat	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Gravol	C	Unknown		Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Oxycodone	C	Unknown		Not Reported
Prednisolone	C	Unknown	20 Milligram	Not Reported
Prednisolone	C	Unknown	10 Milligram	Not Reported
Prednisolone	C	Unknown	20 Milligram	Not Reported
Prednisolone	C	Unknown	10 Milligram	Not Reported
Uloric	C	Unknown	160 Milligram	Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17804544	EXPEDITED (15-DAY)		HO	ES-BAUSCH-BL-2020-014075		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree	Hidrocortisona			S	Intravenous (not otherwise specified)			Not Reported
	Hidroxicloroquina			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17804908	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020196604		64 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, Daily		Pfizer
	Tercian [Cyamemazine Tartrate]			S	Oral	25 Mg, Daily		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, Daily		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, 2x/Day (Every 12h)		Not Reported
	Paroxetine			C	Oral	30 Mg, Daily		Not Reported
	Depakine [Valproic Acid]			C	Oral	1000 Mg, Daily		Not Reported
	Aerius [Desloratadine]			C	Oral	5 Mg, Daily		Not Reported
	Xanax			C	Oral	0.75 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17805077	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020198909		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Azithromycine			S	Oral	500 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17805526	EXPEDITED (15-DAY)		HO	US-AMNEAL PHARMACEUTICALS-2020-AMRX-01419		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Daily		Amneal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17805668	EXPEDITED (15-DAY)		HO	ES-ACCORD-182362		45 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Doxycycline			S	Oral	100 Mg Every 12 Hours		Not Reported
	Azithromycin			S	Oral	500 Mg Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17805673	EXPEDITED (15-DAY)		HO	ES-ACCORD-182373		27 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral			Not Reported
	Ivermectin			S	Oral	12 Mg Du		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Hydroxychloroquine			S	Oral	800 Mg Day (Loading) Followed By 400 Mg Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17811689	DIRECT	N	HO			28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Plaquenil Tab 200mg		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	13113133	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0862		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pneumonia; Prescribed Underdose; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

	Apo-Hydroxyquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	13119212	EXPEDITED (15-DAY)		HO, OT	US-SA-2017SA004994		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Adverse Drug Reaction; Anaphylactic Reaction; Appetite Disorder; Arthralgia; Arthritis Infective; Asthenia; Asthenia; Back Pain; Blister; Chills; Constipation; Contusion; Diarrhoea; Dizziness; Drug Hypersensitivity; Drug Intolerance; Dry Skin; Dysphagia; Dysphoria; Dyspnoea; Ear Pain; Erythema; Fatigue; Gait Disturbance; Haemorrhagic Diathesis; Hallucination; Headache; Hypoaesthesia; Interstitial Lung Disease; Intestinal Obstruction; Joint Swelling; Loss Of Consciousness; Musculoskeletal Stiffness;	Alprazolam			S	Oral	.5 Mg,Tid		Not Reported
	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Lasix			S	Unknown	Unk Unk,Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Isosorbide Dinitrate			S	Unknown	Unk Unk,Unk		Not Reported
	Ampicillin Sodium			S	Unknown	Unk Unk,Unk		Not Reported
	Flagyl			S	Unknown	Unk		Sanofi
	Mesalazine			S	Unknown	Unk		Sanofi
	Citalopram Hydrobromide			S	Unknown	Unk		Not Reported
	Pregabalin			S	Oral	100 Mg,Hs		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Mg,Qd		Not Reported
	Ziprasidone Hydrochloride			S	Unknown	Unk Unk,Unk		Not Reported
	Ciprofloxacin Hydrochloride			S	Unknown	Unk Unk,Unk		Not Reported
	Colchicine			S	Unknown	Unk Unk,Unk		Not Reported
	Prochlorperazine			S	Unknown	Unk Unk,Unk		Not Reported
	Acetazolamide			S	Unknown	Unk Unk,Unk		Not Reported
	Hydromorphone Hydrochloride			S	Unknown	Unk Unk,Unk		Not Reported

Myalgia; Nausea; Neck Pain; Oedema; Oral Pain; Osteoarthritis; Pain; Photophobia; Pruritus; Rash; Rheumatoid Arthritis; Rhinorrhoea; Sjogren'S Syndrome; Skin Disorder; Skin Warm; Sneezing; Tenderness; Thinking Abnormal; Visual Impairment; Vomiting; Weight Decreased; Wheezing; Wound	Doxycycline	S	Unknown	Unk Unk,Unk	Not Reported
	Hydrochlorothiazide/Triamterene	S	Unknown	Unk Unk,Unk	Not Reported
	Erythromycin	S	Unknown	Unk Unk,Unk	Sanofi
	Hepatitis B Vaccine	S	Unknown		Not Reported
	Iron (Salt Not Specified)	S	Unknown	Unk Unk,Unk	Not Reported
	Cefalexin	S	Unknown	Unk Unk,Unk	Not Reported
	Methotrexate	S	Unknown	Unk Unk,Unk	Not Reported
	Potassium Canrenoate	S	Unknown	Unk Unk,Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk Unk,Unk	Sanofi
	Sulfamethoxazole/Trimethoprim	S		Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk Unk,Unk	Not Reported
	Oxcarbazepine	S	Unknown	Unk Unk,Unk	Not Reported
	Tramadol Hydrochloride	S	Unknown	Unk Unk,Unk	Not Reported
	Zenpep	S	Unknown	Unk Unk,Unk	Not Reported
	Enbrel	S	Unknown	Unk Unk,Unk	Not Reported
	Rituxan	S	Unknown	Unk Unk,Unk	Not Reported
	Actemra	S	Unknown	Unk Unk,Unk	Not Reported
	Simponi Aria	S	Unknown	Unk Unk,Unk	Not Reported
	Humira	S	Unknown	Unk Unk,Unk	Not Reported
	Antivert [Meclozine Hydrochloride;Nicotinic Acid]	S	Oral	12.5 Mg,Tid	Not Reported
	Abreva	S		Unk	Not Reported
	Cyclosporine	S	Unknown	Unk Unk,Unk	Not Reported
	Cetylpyridinium Chloride;Dichlorobenzyl Alcohol;Lidocaine Hydrochlorid	S	Unknown	Unk Unk,Unk	Not Reported
	Actifed [Pseudoephedrine Hydrochloride;Triprolidine Hydrochloride]	S		Unk	Not Reported
	Vitamin D2	C	Unknown	Unk Unk,Unk	Not Reported
	Bactroban [Mupirocin]	C	Unknown	Unk Unk,Unk	Not Reported
	Citalopram Hydrobromide	C	Unknown	Unk Unk,Unk	Not Reported

Tamiflu	C	Unknown	Unk Unk,Unk	Not Reported
Tylenol	C	Unknown	Unk Unk,Unk	Not Reported
Singulair	C	Unknown	Unk Unk,Unk	Not Reported
Synthroid	C	Unknown	Unk Unk,Unk	Not Reported
Zoloft	C	Unknown	Unk Unk,Unk	Not Reported
Vitamins Nos	C	Unknown	Unk Unk,Unk	Not Reported
Restasis	C	Unknown	Unk Unk,Unk	Not Reported
Folic Acid	C	Unknown	Unk Unk,Unk	Not Reported
Nasocort	C	Unknown	Unk Unk,Unk	Not Reported
Advair	C	Unknown	Unk Unk,Unk	Not Reported
Prevacid	C	Unknown	Unk Unk,Unk	Not Reported
Flexeril [Cyclobenzaprine Hydrochloride]	C	Unknown	Unk Unk,Unk	Not Reported
Vicodin	C	Unknown	Unk Unk,Unk	Not Reported
Refresh [Carmellose]	C	Unknown	Unk Unk,Unk	Not Reported
Fosamax	C	Unknown	Unk Unk,Unk	Not Reported
Phenergan [Promethazine]	C	Unknown	Unk Unk,Unk	Not Reported
Tazact [Piperacillin Sodium;Tazobactam Sodium]	C	Unknown	Unk Unk,Unk	Not Reported
Vitamin D [Ergocalciferol]	C	Unknown	Unk Unk,Unk	Not Reported
Systane	C	Unknown	Unk Unk,Unk	Not Reported
Zinc	C	Unknown	Unk Unk,Unk	Not Reported
Isopto Tears [Hypromellose]	C	Unknown	Unk Unk,Unk	Not Reported
Mobic	C	Unknown	Unk Unk,Unk	Not Reported
Lamictal	C	Unknown	Unk Unk,Unk	Not Reported
Diamode	C	Unknown	Unk Unk,Unk	Not Reported
Esomeprazole	C	Unknown	Unk Unk,Unk	Not Reported
Calcium Carbonate	C	Unknown	Unk Unk,Unk	Not Reported
Zanaflex	C	Unknown	Unk Unk,Unk	Not Reported
Retin A	C	Unknown	Unk Unk,Unk	Not Reported

Vitamin D3	C	Unknown	Unk Unk,Unk	Not Reported
Hydrocortisone	C	Unknown	Unk Unk,Unk	Not Reported
Zaditor [Ketotifen]	C	Unknown	Unk Unk,Unk	Not Reported
Rubramin	C	Unknown	Unk Unk,Unk	Not Reported
Zantac	C	Unknown	Unk Unk,Unk	Not Reported
Deltasone [Dexamethasone]	C	Unknown	Unk Unk,Unk	Not Reported
Vitamin B12 [Cyanocobalamin]	C	Unknown	Unk Unk,Unk	Not Reported
Protopic	C	Unknown	Unk Unk,Unk	Not Reported
Flu Vaccine Vii	C		Unk	Not Reported
Pneumococcal Vaccine	C		Unk	Not Reported
Norco	C		Unk	Not Reported
Esomeprazole Magnesium	C		Unk	Not Reported
Deltasone [Prednisone]	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	13228895	EXPEDITED (15-DAY)		OT	CA-ROCHE-1832720		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Breast Cancer; Condition Aggravated; Contraindicated Product Administered; Drug Intolerance; Fatigue; Hand Deformity; Headache; Infection; Joint Swelling; Loss Of Consciousness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown	Therapy Duraiton: 5 Years		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Methotrexate	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Gold	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Leflunomide	S	Oral		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Sodium Aurothiomalate	S	Parenteral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	14351652	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268415		78 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Grip Strength Decreased; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	Unk Unk,Unk		Sanofi
	Leflunomide			S	Oral	20 Mg,Qd		Sanofi
	Prednisone			S	Unknown	20 Mg,Unk		Not Reported
	Prednisone			S	Unknown	40 Mg,Qd		Not Reported
	Sulfasalazine			S	Oral	2 Mg, Qd		Not Reported
	Enbrel			S	Unknown	Unk Unk,Qw		Not Reported
	Methotrexate Sodium			S	Subcutaneous	15 Mg, 1 Every 1 Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	14875538	EXPEDITED (15-DAY)		OT	CA-SA-2018SA126619			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Hydroxychloroquine Sulfate			S	Oral	400 Mg,Qd		Sanofi
	Arava			S	Oral	20 Mg,Unk		Sanofi
	Sulfasalazine			S	Unknown	500 Mg		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg,Qd		Sanofi
	Humira			S	Subcutaneous	40 Mg,Qow		Not Reported

Methotrexate Sodium	S	Unknown	25 Mg,Qw		Not Reported
Orencia	S	Unknown	Unk Unk,Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
Simponi	S	Subcutaneous	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	15193064	EXPEDITED (15-DAY)		OT	CA-ROCHE-2159066			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	15268954	EXPEDITED (15-DAY)		HO	CA-ROCHE-2168145			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Viral Infection	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	15275893	EXPEDITED (15-DAY)		OT	CA-ROCHE-2168133			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculin Test Positive	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Amoxil [Amoxicillin]			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Leflunomide			C	Unknown			Not Reported
	Amoxicillin Trihydrate;Clavulanate Potassium			C				Not Reported
	Adalimumab			C				Not Reported
	Bcg			C				Not Reported

	Clavulanate Potassium	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	15354415	EXPEDITED (15-DAY)		OT	CA-ROCHE-2180456		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	15390537	EXPEDITED (15-DAY)		OT	CA-ROCHE-2185424			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

	Sulfasalazine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	15705892	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20181205173			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Multiple Allergies; Nausea; Off Label Use; Product Use Issue; Rash; Therapeutic Product Effect Decreased	Levaquin			S	Unknown			Not Reported
	Avelox			S	Unknown			Not Reported
	Biaxin			S	Unknown			Not Reported
	Keflex			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Losartan			S	Unknown			Not Reported
	Hydralazine Hydrochloride			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cephalexin Monohydrate			S	Unknown			Not Reported
	Cephalexin			S	Unknown			Not Reported
	Enalapril			S	Unknown			Not Reported
	Enalapril Maleate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported
	Hctz			S	Unknown			Not Reported
	Hydrochlorothiazide			S	Unknown			Not Reported
	Isoniazid			S	Unknown			Not Reported
	Losartan Potassium			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Metoprolol Tartrate			S	Unknown			Not Reported
	Moxifloxacin Hydrochloride			S	Unknown			Not Reported

Orencia	S	Unknown	Not Reported
Pariet	S	Unknown	Not Reported
Penicillin G /00000902/	S	Unknown	Not Reported
Penicillin G /00000903/	S	Unknown	Not Reported
Plaquenil S	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Ciprofloxacin	S	Unknown	Not Reported
Pantoprazole Magnesium	S	Unknown	Not Reported
Tecta	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Venofer	C	Unknown	Not Reported
Esomeprazole	C	Unknown	Not Reported
Hydroxychloroquine	C	Unknown	Not Reported
Atenolol	C	Unknown	Not Reported
Colchicine	C	Unknown	Not Reported
Coversyl	C	Unknown	Not Reported
Leucovorin	C	Unknown	Not Reported
Levothyroxine Sodium	C	Unknown	Not Reported
Ranitidine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	16199830	EXPEDITED (15-DAY)		DS, HO, OT	CA-009507513-1904CAN006247		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Adverse Event; Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase; Aspartate Aminotransferase	Fosamax			S	Unknown	70 Milligram, Qw (1 Every 1 Week)		Merck
	Fosamax			S	Unknown	70 Milligram, 1 Every 1 Week		Merck
	Fosamax			S	Unknown	Unk		Merck
	Fosamax			S	Unknown	70 Milligram, 4 Every 1 Week		Merck

Increased; Asthenia;	Fosamax	S	Unknown	70 Milligram	Merck
Asthma; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Body Temperature Decreased;	Actemra	S	Intravenous (not otherwise specified)	360.0 Milligram,Qm (1every 1 Month) (Also Reported As Every 4 Weeks)	Not Reported
Bone Lesion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Chills; Condition Aggravated; Contraindicated Product Administered; Contusion; Cough; Deep Vein Thrombosis; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Dysphonia; Dyspnoea; Enthesopathy; Erythema; Fall; Fatigue; Gastric Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Granuloma Skin; Headache; Heart Rate Increased; Hypercalcaemia; Hypersensitivity; Infection; Inflammation; Influenza; Infusion Related Reaction; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Lower Respiratory Tract Infection; Muscular Weakness; Musculoskeletal Stiffness; Mycotic Allergy; Nausea; Off Label Use; Pain; Pain In Extremity; Panniculitis;	Actemra	S	Intravenous (not otherwise specified)	680.0 Milligram, 1 Every 1 Month(Also Reported As Every 4 Weeks)	Not Reported
	Actemra	S	Unknown	680.0 Milligram	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	2.68 Milligram, 1 Every 4 Weeks	Not Reported
	Actemra	S		360 Milligram 1 Every 1 Month; Dosage Form: Not Specified	Not Reported
	Actemra	S	Unknown	680 Milligram 1 Every 1 Months (Dosage Form: Not Specified)	Not Reported
	Actemra	S		360.0 Milligram	Not Reported
	Alendronic Acid	S	Unknown	70 Milligram, Qw (1 Every 1 Week)	Not Reported
	Alendronic Acid	S	Unknown	70.0 Milligram, 1 Every 1 Week	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25.0 Milligram,Biw (2 Every 1 Week)	Not Reported
	Enbrel	S	Unknown	25 Milligram , (1 Every 2 Weeks)	Not Reported
	Enbrel	S	Unknown	50.0 Milligram, Qw(1 Every 1 Week)	Not Reported
	Enbrel	S	Subcutaneous	25.0 Milligram, Qw (1 Every 1 Week)	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25.0 Milligram	Not Reported
	Enbrel	S	Unknown	50.0 Milligram	Not Reported

Peripheral Swelling; Product Use Issue; Productive Cough; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Respiratory Tract Congestion; Rheumatoid Arthritis; Rheumatoid Nodule; Rhinorrhoea; Skin Necrosis; Skin Ulcer; Speech Disorder; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Tongue Disorder; Ulcer	Enbrel	S	Unknown	25 Milligram, 1 Every 1 Weeks	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	40.0 Milligram,Biw (1 Every 2 Weeks)	Not Reported
	Humira	S	Subcutaneous	40 Milligram 11 Every 2 Weeks	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200.0 Milligram, Qd (1 Every 1 Day)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	20.0 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	360 Milligram 1 Every 1 Months	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	680 Milligram	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Unknown	12.0 Milligram, Every 4 Weeks(1every4week)	Not Reported
	Methotrexate	S	Unknown	15.0 Milligram, (1every 4week)	Not Reported
	Methotrexate	S	Unknown	17.5 Milligram, Qw (1 Every 1 Week)	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, Qw (1 Every 1 Week)	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qw (1 Every 1 Week)	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, Qw (1 Every 1 Week)	Not Reported

Methotrexate	S	Subcutaneous	12 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Subcutaneous	15.5 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Unknown	10 Milligram, (1 Every 4 Weeks)	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, (1 Every 4 Weeks)	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, (1 Every 4 Weeks)	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, (1 Every 4 Weeks)	Not Reported
Methotrexate	S	Unknown	12 Milligram, (1 Every 1 Weeks)	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Unknown	12 Milligram	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Oral	10 Milligram, (1 Every 4 Weeks)	Not Reported
Methotrexate	S	Unknown	10.0 Milligram	Not Reported
Methotrexate	S	Oral	25 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Oral	12.5 Milligram	Not Reported
Methotrexate	S	Unknown	12.5 Milligram	Not Reported
Methotrexate	S	Unknown	15 Milligram, 1 Every 1 Weeks	Not Reported

Methotrexate	S	Oral	10 Milligram, 1 Every 1 Weks	Not Reported
Methotrexate	S	Unknown	10.0 Milligram, 1 Every 1 Weeks	Not Reported
Methotrexate	S	Unknown	70 Milligram, Qw (1 Every 1 Week)	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Qm (1 Every 1 Month)	Not Reported
Myochrysine	S	Parenteral	50 Milligram, Qm (1 Every 1 Month)	Not Reported
Myochrysine	S	Intramuscular	25.0 Milligram, Qw (1 Every 1 Week)	Not Reported
Myochrysine	S	Parenteral	Unk	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, 1 Every 2 Weeks	Not Reported
Myochrysine	S	Intramuscular	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	780.0 Milligram, Qw(1every1week)	Not Reported
Orencia	S	Unknown	760 Milligram, Qw (1 Every 1 Week)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	780 Mg, 1 Every 1 Weeks (Therapy Duration: 366 (Units Not Provided))	Not Reported
Simponi	S	Unknown	360.0 Milligram, Qm (1 Every 1 Month)	Not Reported
Simponi	S	Subcutaneous	680.0 Milligram, Qm (1 Every 1 Month)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Unknown	Unk, Dosage Form Reported As Powder For	Not Reported

			Solution Intravenous	
Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 365.0 (Units Not Provided)	Not Reported
Rituxan	S	Intravenous drip	1000 Milligram, 2 Every1 Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	1000.0 Milligram (2 Every 1 Day)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000.0 Milligram (1 Every 12hour(S))	Not Reported
Sulfasalazine	S	Unknown	500 Milligram, Dosage Form Reported As Not Specified	Not Reported
Sulfasalazine	S	Unknown	780 Milligram, 1 Every 1 Weeks (Therapy Duration: 366 (Units Not Provided))	Not Reported
Sulfasalazine	S	Endocervical	Unk	Not Reported
Sulfasalazine	S	Unknown	780 Milligram, Qw	Not Reported
Sulfasalazine	S	Endocervical	Unk, Dosage Form Reported As Not Specified	Not Reported
Arava	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk, Single-Use Pre-Filled Syringe, Dosage Form Reported As Solution Subcutaneous	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	680 Milligram, 1 Every 4 Weeks	Not Reported
Tocilizumab	S	Unknown	380 Milligram	Not Reported
Tocilizumab	S	Unknown	360 Milligram, 1 Every 1 Months	Not Reported
Etanercept	S	Unknown	25 Milligram 1 Every 1	Not Reported

			Wek	
Etanercept	S	Unknown	25.0 Milligram 2 Every 1 Wek	Not Reported
Etanercept	S	Unknown	50 Milligram 1 Every 1 Wek	Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S			Not Reported
Cosentyx	S	Subcutaneous	300 Milligram, Qm	Not Reported
Cosentyx	S	Subcutaneous	300 Milligram, Qm	Not Reported
Ergocalciferol	S	Unknown	Dosage Form: Not Specified	Not Reported
Pantoprazole	S	Unknown	Dosage Form: Not Specified	Not Reported
Apo Ibuprofen	S	Oral	Unk	Not Reported
Apo Ibuprofen	S			Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Apremilast	S	Unknown	60 Milligram 2 Every 1 Days	Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Apremilast	S	Unknown	60 Milligram	Not Reported
Ibuprofen	S		600 Milligram; Dosage Form: Not Specified	Not Reported
Ibuprofen	S	Oral	600 Milligram 1 Every 1 Days	Not Reported
Ibuprofen	S	Oral	Unk, Qd	Not Reported
Stelara	S	Subcutaneous	Unk, Dosage Form Reported As Solution Subcutaneous	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Otezla	S	Unknown		Not Reported
Rituximab	S			Not Reported

Cyclosporine	S	Unknown	150.0 Milligram, Q24h (1every24hours) (1 Every 1 Day)	Not Reported
Cyclosporine	S	Unknown	Unk	Not Reported
Cyclosporine	S	Unknown	150.0 Milligram,1 Every 24 Hours	Not Reported
Motrin (Ibuprofen)	S		600 Milligram, Qd	Not Reported
Motrin (Ibuprofen)	S		600 Milligram, Qd	Not Reported
Prednisone	C	Unknown	10.0 Milligram, Q24h(1every24 Hours) (1 Every 1 Day)	Not Reported
Prednisone	C	Unknown	10 Milligram, Q2h (1 Every 2 Hours)	Not Reported
Prednisone	C	Unknown	10.0 Milligram	Not Reported
Prednisone	C	Unknown	20.0 Milligram	Not Reported
Prednisone	C	Unknown	10.0 Milligram, Qd (1 Every 1 Day)	Not Reported
Prednisone	C	Unknown	Dosage Form: Not Specified	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	5.0 Milligram, Bid (2 Every 1 Day)	Not Reported
Xeljanz	C	Oral	5.0 Milligram, Bid (2 Every 1 Day)	Not Reported
Prednisolone	C	Unknown	Unk	Not Reported
Prednisolone	C	Unknown	10.0 Milligram 1 Every 1 Days	Not Reported
Fosamax	C	Unknown	70 Milligram 1 Every 1 Week	Merck
Hydroxychloroquine Sulfate	C	Oral	Unk, 1 Every 1 Days	Not Reported
Hydroxychloroquine Sulfate	C	Oral	200 Gram, 2 Every 1 Days	Not Reported
Hydroxychloroquine Sulfate	C	Oral	200 Gram, 2 Every 1 Days	Not Reported
Naproxen	C	Unknown	Dosage Form: Not	Not Reported

			Specified	
Plaquenil	C	Unknown		Not Reported
Simponi	C	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
Sulfasalazine	C	Unknown	Dosage Form: Not Specified	Not Reported
Symbicort	C	Unknown		Not Reported
Tramadol Hydrochloride	C	Unknown		Not Reported
Benadryl	C	Unknown	Unk, Dosage Form Reported As Not Specified	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Colchicine	C	Oral	Unk	Not Reported
Dexilant	C	Unknown		Not Reported
Dexilant	C	Unknown		Not Reported
Febuxostat	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Gravol (Dimenhydrinate)	C	Unknown	Unk, Dosage Form Reported As Not Specified	Not Reported
Gravol (Dimenhydrinate)	C	Unknown	Unk	Not Reported
Mogadon	C	Oral	5 Milligram	Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Oxycodone	C	Unknown		Not Reported
Uloric	C	Unknown	80 Milligram Two Every 1 Days	Not Reported
Uloric	C	Unknown	80 Unk	Not Reported
Cyclosporine	C	Unknown	Dosage Form Not Specified	Not Reported
Cyclosporine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	16823349	EXPEDITED (15-DAY)		OT	CA-SAKK-2019SA185374AA		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Sarilumab			S				Sanofi
	Cortisone Acetate			S				Not Reported
	Desoximetasone			S				Sanofi
	Diclofenac Sodium			S				Not Reported
	Topicort			S	Cutaneous			Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Prednisone			S		Unk		Not Reported
	Arava			S	Oral	Unk		Sanofi
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S				Not Reported
	Desoximetasone			S	Oral			Sanofi
	Alendronate Sodium			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Hydroxychloroquine Sulfate			S		1 Df, Qd		Sanofi
	Leflunomide			S	Oral			Sanofi
	Methotrexate			S		Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	1 Df, Qd		Not Reported
	Plaquenil			S	Oral	1 Df, Qd		Sanofi
	Prednisone			S				Not Reported
	Pseudoephedrine Hydrochloride			S				Sanofi
	Paracetamol			S				Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Hydrocortisone Acetate			S	Subcutaneous			Sanofi
	Folic Acid			S				Not Reported
	Stelara			S				Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Methotrexate Sodium	S	Oral			Not Reported
Golimumab	S				Not Reported
Cimzia	S	Subcutaneous	Unk, Qd		Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Phthalylsulfathiazole	S				Not Reported
Hydroxychloroquine	S		Unk		Not Reported
Hydroxychloroquine	S	Oral	1 Df, Qd		Not Reported
Actemra	S				Not Reported
Simponi	S	Subcutaneous			Not Reported
Humira	S	Subcutaneous			Not Reported
Atasol [Paracetamol]	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	16849610	EXPEDITED (15-DAY)		OT	CA-ROCHE-2411011		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Off Label Use; Pneumonia	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenou		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported

	Apo-Leflunomide		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17233191	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508660		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nephrolithiasis; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 823.0		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 823.0		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 823.0		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral	Therapy Duration:		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	Therapy Duration: 6.0 Months		Not Reported
	Tylenol			S	Unknown			Not Reported
	Acetaminophen;Diphenhydramin			S	Unknown			Not Reported

e Hydrochloride			
Celebrex	C	Unknown	Not Reported
Hydromorphone Hydrochloride	C	Unknown	Not Reported
Meloxicam	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Tylenol W/Codeine No. 3	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Acetaminophen;Codeine Phosphate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17250742	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514001		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Arthralgia; Chronic Sinusitis; Diverticulum; Drug Ineffective; Haemochromatosis; Impaired Work Ability; Irritable Bowel Syndrome; Joint Swelling; Nausea; Osteoporosis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17299256	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524986		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Intolerance; Fatigue; Treatment Failure	Ciclosporin	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Neoral	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz Xr	C		Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17333671	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530860		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Red Blood Cell Sedimentation	Actemra			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported

Rate Abnormal; Treatment Failure	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Infliximab	S	Unknown		Not Reported
	Kineret	S	Subcutaneous	Solution Subcutaneous, 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes	Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown		Not Reported
	Prednisone	C			Not Reported
	Desoximetasone	C			Not Reported
	Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17358367	EXPEDITED (15-DAY)		HO	CA-ROCHE-2530347		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Gabapentin			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Celecoxib			S	Oral			Not Reported
	Celecoxib			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Fentanyl Matrix	S	Unknown	Not Reported
	Gabapentin	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Nortriptyline	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Oxycontin	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Nasonex	C	Unknown	Not Reported
	Aclasta	C	Unknown	Not Reported
	Actonel	C	Unknown	Not Reported
	Ascorbic Acid	C		Not Reported
	Biotin	C		Not Reported
	Calcium	C	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Esomeprazole	C		Not Reported
	Fentanyl	C	Unknown	Not Reported
	Ferrous Gluconate	C	Unknown	Not Reported
	Fish Oil	C	Unknown	Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C		Not Reported
	Loperamide	C		Not Reported
	Esomeprazole	C		Not Reported
	Nortriptyline	C	Unknown	Not Reported
	Omega 3 [Docosahexaenoic	C		Not Reported

Acid;Eicosapentaenoic Acid]				
Omega 3-6-9 [Fish Oil]	C	Unknown		Not Reported
Oxycodone Terephthalate	C	Unknown		Not Reported
Pantoprazole	C	Unknown		Not Reported
Prednisone	C			Not Reported
Pyridoxine	C			Not Reported
Sodium	C			Not Reported
Thiamine Hcl	C			Not Reported
Trazodone	C			Not Reported
Tylenol	C			Not Reported
Vitamin A [Retinol]	C			Not Reported
Vitamin B3	C	Unknown		Not Reported
Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17425017	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0812		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Kineret			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Desoximetasone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17433128	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0819		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Kineret			S	Unknown			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Gold			S	Intramuscular			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S				Not Reported
	Imuran			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17443585	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552671		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Vaccine; Condition Aggravated; Diarrhoea; Drug Ineffective; Fall; Hypersensitivity; Laryngeal Disorder; Nausea; Product Use Issue; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17580328	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0808		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; No Adverse Event; Prescribed Underdose; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Kineret			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Dextromethorphan Hydrobromide			S	Unknown			Not Reported
	Eletriptan Hydrobromide			S				Not Reported
	Eletriptan Hydrobromide			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Orencia	S	Intravenous (not otherwise specified)	0.75 Mg Once Monthly	Not Reported
Rituximab	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz Xr	S	Unknown		Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Every 1 Month	Not Reported
Apo-Azathioprine	S	Unknown		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Azathioprine	S	Unknown		Not Reported
Azathioprine	S			Not Reported
Celebrex	S	Unknown		Not Reported
Celebrex	S	Unknown		Not Reported
Celecoxib	S	Unknown		Not Reported
Celecoxib	S	Unknown		Not Reported
Etanercept	S	Subcutaneous		Not Reported
Plaquenil	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported

Methotrexate	S	Subcutaneous		Not Reported
Prednisone	S	Unknown		Not Reported
Calcium	C	Oral		Not Reported
Dilaudid	C	Unknown		Not Reported
Dilaudid	C	Unknown		Not Reported
Ergocalciferol	C	Unknown		Not Reported
Hydromorph Contin	C	Unknown		Not Reported
Hydromorph Contin	C	Unknown		Not Reported
Acetaminophen/Codeine Phosphate	C	Unknown		Not Reported
Altace	C	Unknown		Not Reported
Altace	C	Unknown		Not Reported
Apo-Gabapentin	C	Oral		Not Reported
Apo-Gabapentin	C	Unknown		Not Reported
Atorvastatin Calcium	C	Oral		Not Reported
Atorvastatin Calcium	C	Oral		Not Reported
Cipralex	C	Unknown		Not Reported
Citalopram Hydrobromide	C	Unknown		Not Reported
Conjugated Estrogens	C	Unknown	Dose: 0.625 Mg	Not Reported
Conjugated Estrogens	C	Unknown		Not Reported
Escitalopram	C	Unknown		Not Reported
Estrace	C	Unknown	Dose: 0.5 Mg	Not Reported
Gabapentin	C	Oral		Not Reported
Gabapentin	C	Unknown		Not Reported
Cymbalta	C	Unknown		Not Reported
Cymbalta	C	Unknown		Not Reported
Cymbalta	C	Unknown		Not Reported
Hydrochlorothiazide	C	Unknown	Dose: 12.5 Mg	Not Reported
Hydromorphone Hcl	C	Oral		Not Reported
Hydromorphone Hcl	C	Oral		Not Reported

	Mupirocin	C	Topical	Not Reported
	Pantoloc	C	Unknown	Not Reported
	Shark Liver Oil	C	Unknown	Not Reported
	Tapentadol Hydrochloride	C	Unknown	Not Reported
	Taro-Mupirocin	C	Topical	Not Reported
	Tramacet	C	Oral	Not Reported
	Tramadol Hydrochloride	C	Oral	Not Reported
	Vitamin D	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17696997	EXPEDITED (15-DAY)		HO, OT	BE-ADVANZ PHARMA-202004003502			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Off Label Use; Rhabdomyolysis	Hydroxychloroquine			S	Oral	400 Mg, Bid, Film-Coated Tablet		Concordia
	Hydroxychloroquine			S	Oral	200 Mg, Bid, Film-Coated Tablet		Concordia
	Haldol			C		Unk		Not Reported
	Paracetamol			C		1 Unk		Not Reported
	Fraxiparine			C		Unk		Not Reported
	Dafalgan Forte			C		1 G		Not Reported
	Morphine			C		10 Mg/Ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17701011	EXPEDITED (15-DAY)		DE	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-244837		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Levofloxacin			S	Unknown	Unk		Ranbaxy
	Azithromycin			S	Oral	500 Milligram, Daily		Sun

	Hidroxicloroquina Sulfato (2143su)	S	Oral	200 Milligram, Daily	Not Reported
	Hidroxicloroquina Sulfato (2143su)	S			Not Reported
	Lopinavir+Ritonavir	S	Oral	2 Dosage Form, Bid	Not Reported
	Tacrolimus (2694a)	S	Oral	Unk	Not Reported
	Enoxaparina Sodica (2482so)	C	Subcutaneous	40 Milligram, Daily	Not Reported
	Prednisona (886a)	C	Oral	20 Milligram, Daily	Not Reported
	Ceftriaxona (501a)	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17718685	EXPEDITED (15-DAY)		DS, OT	CA-COLGATE PALMOLIVE COMPANY-20200400745			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Confusional State; Contraindicated Product Administered; Contusion; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Infusion Related	Chlorhexidine Unspecified			S	Unknown			Colgate
	Periogard Alcohol Free Rinse			S	Buccal	Alcohol Free		Colgate
	Chlorhexidine Gluconate Unspecified			S	Unknown	Oral Rinse		Colgate
	Oxycodone			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)	3011.2 Milligram		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	2912 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728 Milligram		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Reaction; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Pain; Pemphigus; Pericarditis; Peripheral Swelling; Pregnancy; Pruritus; Pyrexia; Rash; Rheumatoid Arthritis; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Weight Increased; Wound	Methotrexate	S	Oral	20 Milligram 1 Day	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Oral	20 Milligram 1 Week	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Acetaminophen	S	Unknown		Not Reported
	Cortisone	S	Topical	25 Milligram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	500 Milligram	Not Reported
	Sulfasalazine	S	Oral	2000 Milligram	Not Reported
	Phthalylsulfathiazole	S	Oral	500 Milligram	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Oral	2000 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	500 Milligram, Cyclical	Not Reported
	Oxycodone Terephthalate	S			Not Reported
	Sulfamethoxazole	S			Not Reported
	Fosamax	S	Oral		Not Reported
	Oxycodone;Paracetamol	S	Unknown		Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Cetirizine	S	Unknown	10 Milligram	Not Reported
	Prednisone	S	Oral	7.5 Milligram	Not Reported
	Diclofenac	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported

Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram	Not Reported
Cimzia	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Tofacitinib Citrate	S	Unknown	10 Milligram	Not Reported
Sulfamethoxazole And Trimethoprim	S			Not Reported
Arava	S	Oral	20 Milligram	Not Reported
Chloraprep	S		Topical	Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous		Not Reported
Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Leflunomide	S	Oral		Not Reported
Oxycodone Hydrochloride	S			Not Reported
Tofacitinib	S	Unknown	10 Milligram	Not Reported
Reactine [Cetirizine Hydrochloride]	C			Not Reported
Salazopyrin	C	Unknown		Not Reported
Pantoprazole Sodium	C			Not Reported
Pantoloc [Pantoprazole]	C			Not Reported
Cetirizine Dihydrochloride	C			Not Reported
Paracetamol/Codeine	C			Not Reported
Atasol [Paracetamol]	C	Unknown		Not Reported
Tylenol With Codeine	C			Not Reported
Tylenol [Paracetamol]	C			Not Reported
Desogestrel And Ethinylestradiol	C			Not Reported
Ibuprofen	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17750410	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2020-ES-1230308		26 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Psychosis; Suicide Attempt	Hidroxicloroquina (2143a)	S	Oral	400 Milligram Daily;	Teva
	Alopurinol 100 Mg Comprimido	C	Oral	100 Mg	Not Reported
	Paracetamol (12a)	C	Oral	1 Gram 8 Hours	Not Reported
	Famotidina 20 Mg Comprimido	C	Oral	20 Mg	Not Reported
	Doxazosina (2387a)	C	Oral	4 Mg	Not Reported
	Ceftriaxona 2.000 Mg Inyectable Iv	C	Intravenous (not otherwise specified)	2 Gram	Not Reported
	Cefixima (2400a)	C	Oral	200 Mg 12 Hours	Not Reported
	Magnogene 53 Mg Comprimidos Recubiertos	C	Oral	106 Mg	Not Reported
	Prednisona (886a)	C	Oral	20 Mg	Not Reported
	Prednisona (886a)	C		5 Mg	Not Reported
	Prednisona (886a)	C	Oral	20 Mg	Not Reported
	Carvedilol 25 Mg Comprimido	C	Oral	25 Mg	Not Reported
	Zemplar 1 Microgramo Capsulas Blandas	C	Oral	1 Microgram	Not Reported
	Myfortic 360 Mg Comprimidos Gastrorresistentes	C	Oral	360mg 12 Hours	Not Reported
	Enoxaparina Sodio 20 Mg (2.000 Ui) Inyectable 0,2 Ml	C	Subcutaneous	20 Mg	Not Reported
	Fosrenol	C	Oral	750 Mg 12 Hours	Not Reported
	Metamizol 575 Mg Capsula	C	Oral	575 Mg	Not Reported
	Tacrolimus (2694a)	C	Oral	2 Mg	Not Reported
	Tacrolimus (2694a)	C	Oral	2 Mg	Not Reported
	Tacrolimus (2694a)	C	Oral	1 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17765762	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437414		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint	Remicade			S	Intravenous (not otherwise specified)			Janssen

Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Simponi	S	Subcutaneous	Janssen
	Actemra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Desoximetasone	C		Not Reported
	Methotrexate	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17767549	EXPEDITED (15-DAY)		HO	FI-BAUSCH-BL-2020-013895			Unknown	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Pneumonia Streptococcal	Prednisolone			S	Unknown	2 Subjects; Combination With Mtx, And Bdmard; Combination With Mtx, And Certolizumab (Third Bdmard)		Not Reported
	Prednisolone			S	Unknown	One Subject; Combination With Leflunomide, And Hydroxychloroquine		Not Reported
	Methotrexate			S	Unknown	Two Subjects		Not Reported
	Methotrexate			S				Not Reported
	Leflunomide			S	Unknown	One Subject		Not Reported
	Hydroxychloroquine			S	Unknown	One Subject		Not Reported
	Certolizumab			S	Unknown	Third Bdmard; One Subject		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17801320	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595664		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Cataract Operation; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral	2.0 Years		Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17804850	EXPEDITED (15-DAY)		HO	IT-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-037471		89 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticoagulation Drug Level Increased; Drug Interaction	Apixaban			S	Oral	2.5 Milligram, Bid		Bristol Myers Squibb
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lopinavir/Ritonavir			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17804885	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2602052		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17804897	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1236797		24 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S	Oral	400 Mg		Teva
	Lopinavir/Ritonavir Sandoz 200 Mg/50 Mg Comprimidos Recubiertos Con Pe			S	Oral	4 Dosage Forms Daily; 200 Mg / 50 Mg		Not Reported
	Interferon Beta-1b (2305od)			S	Subcutaneous	0.25 Mg		Not Reported
	Cloroquina [Chloroquine]			S	Oral	310 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17804903	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600819		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous	Single Use Solution		Not Reported
	Enbrel			S	Unknown	1.0 Dosage Forms		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arava			C	Unknown			Not Reported
	Codeine Phosphate			C	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17804959	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599174		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single Use Prefilled Syringe		Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17805027	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598757			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17805206	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598696		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Remicade	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17805222	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598386		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Oral			Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Cymbalta			C				Not Reported
	Hydromorphone			C				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17805262	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-2062		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fall; Gait Inability; Malaise; Paralysis; Spinal Fracture	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17805480	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598565		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Risedronate Sodium			S	Unknown			Not Reported
	Risedronic Acid			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17805682	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599992			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Pulmonary Toxicity	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17805708	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202004004352			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S		Unk		Concordia
	Dupixent			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17805768	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601279			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Intentional Product Use	Rituximab			S	Unknown			Not Reported

Issue; Off Label Use; Rheumatoid Arthritis	Doxycycline	S	Unknown	Not Reported
	Doxycycline Hyclate	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17805795	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-247183		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cornea Verticillata	Hydroxychloroquine			S	Unknown	600 Milligram, Bid		Sun
	Hydroxychloroquine			S	Unknown	1200 Milligram		Sun
	Everolimus			C	Unknown	10 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17805801	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598742		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthrodesis; Condition Aggravated; Cough; Drug Ineffective; Headache; Rheumatoid Arthritis; Viral Infection	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17805865	EXPEDITED (15-DAY)		HO, OT	CH-IPCA LABORATORIES LIMITED-IPC-2020-CH-001562			Unknown	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Haemolysis; Off Label Use	Amoxicillin & Clavulanate Potassium			S	Unknown	1.2 Gram, Qid		Not Reported
	Hydroxychloroquine			S	Unknown	600 Milligram, Single		Ipca
	Piperacillin/Tazobactam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17805867	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602952			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17805896	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598821			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Off Label Use; Therapeutic Product Effect Incomplete	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17805934	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598728		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Leflunomide			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806026	EXPEDITED (15-DAY)		DE	FR-ABBVIE-20K-056-3408720-00		76 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Coronavirus Infection; Septic Shock	Kaletra 200/50			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806046	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598842		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Insulin			C	Oral			Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Lozide [Indapamide]			C	Unknown			Not Reported

	Metformin		C	Unknown	Not Reported
	Prednisone		C		Not Reported
	Ramipril		C		Not Reported
	Naproxen		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806054	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598554			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Factor Positive; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806078	EXPEDITED (15-DAY)		HO	ES-ACCORD-182452		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Gastrointestinal Haemorrhage; Hepatitis Acute	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Enoxaparin			S	Subcutaneous	60 Mg Cada 12 Horas		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Mg Daily For 6 Days Followed By 10 Mg Daily X 5 Days		Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806221	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598032		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Joint Swelling; Off Label Use; Synovitis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Amitriptyline Hydrochloride			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Premarin			C	Unknown			Not Reported
	Sumatriptan Succinate			C	Unknown			Not Reported
	Tenormin			C	Unknown			Not Reported
	Tofacitinib			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806227	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236784			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated	Methotrexate Sodium			S	Unknown			Barr

Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulphathiazole	S	Unknown	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806260	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598086		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hypersensitivity; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness;	Actemra			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Off Label Use; Peripheral Swelling; Rash; Tendon Disorder	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Hydroxychloroquine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806262	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-014818			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Metronidazole			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Bausch And Lomb
	Erythromycin			S	Unknown			Bausch And Lomb
	Demerol			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Erythromycin Base			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Norfloxacin			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Arthrotec			S				Not Reported
	Ceclor			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Lyrica			S	Unknown			Not Reported

	Meperidine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806269	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600489		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Dysphonia; Dyspnoea; Intentional Product Use Issue; Odynophagia; Off Label Use; Rheumatoid Arthritis; Stridor	Rituximab			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806334	EXPEDITED (15-DAY)		DS	CA-ROCHE-2598098		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disability; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Rash; Skin Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Actemra			S	Intravenous (not otherwise specified)	Not Specified		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

	Orencia	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone Acetate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Ergocalciferol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806352	EXPEDITED (15-DAY)		DS	CA-ROCHE-2598841		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Wheelchair User	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Folic Acid			C				Not Reported

	Methotrexate		C			Not Reported
	Prednisone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806362	EXPEDITED (15-DAY)		DE, OT	US-ADVANZ PHARMA-202005005325			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Off Label Use	Hydroxychloroquine			S		Unk		Concordia
	Zpac			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806482	EXPEDITED (15-DAY)		OT	ES-ACCORD-182526		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Sulpiride			S	Oral	50 Mg Every 8 Hours		Not Reported
	Enoxaparin			S	Subcutaneous	40 Mg Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806634	EXPEDITED (15-DAY)		HO	ES-ACCORD-182639		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage; Off Label Use; Vessel Puncture Site Haemorrhage	Hydroxychloroquine			S	Oral	400 Mg		Not Reported
	Enoxaparin			S	Subcutaneous	40 Mg		Not Reported
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Mg Dia		Not Reported
	Lysine Acetylsalicylate			S	Intravenous (not otherwise specified)	200 Mg		Not Reported
	Adiro			S	Oral	1 Cp Day, 100 Mg Gastro-Resistant Tablets Efg, 500 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806646	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1237680		67 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Rash Pruritic	Levofloxacino (2791a)			S	Intravenous (not otherwise specified)	500 Mg		Teva
	Hidroxicloroquina Sulfato (2143su)			S	Oral	200 Mg		Teva
	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	2 Dosage Forms		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17806764	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598504			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807048	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599975		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Ciclosporin	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Neoral	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807119	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599986			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807129	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599020		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Off Label Use; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cyclobenzaprine			C	Unknown			Not Reported
	Cyclobenzaprine			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone Acetate			C	Unknown			Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807174	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598813		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807176	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598589			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Gait Disturbance; Myocardial Infarction; Pain; Swelling; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Codeine Sulfate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807183	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598569		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Intestinal Perforation	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807189	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598518			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Intentional Product Use Issue; Off Label Use; Pneumonia	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807193	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-		60 YR	Male	ESP

2020RR-247372

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome	Azithromycin			S	Oral	500 Mg Dia		Sun
	Hidroxicloroquina (2143a)			S	Oral	400 Mg Dia		Not Reported
	Roactemra			C	Intravenous (not otherwise specified)	600 Mg ; In Total		Not Reported
	Ceftriaxona (501a)			C	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807204	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598566			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807237	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598649			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Darifenacin			C	Unknown			Not Reported
	Darifenacin Hydrobromide			C				Not Reported
	Desoximetasone			C				Not Reported
	Dilaudid			C	Unknown			Not Reported
	Diphenhydramine			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported
	Kadian			C	Unknown			Not Reported

Loperamide	C	Not Reported
Morphine Sulfate	C	Not Reported
Vagifem	C	Not Reported
Urispas	C	Not Reported
Trimethoprim	C	Not Reported
Synthroid	C	Not Reported
Omnaris	C	Not Reported
Oxyneo	C	Not Reported
Pantoloc [Pantoprazole]	C	Not Reported
Pantoprazole Sodium	C	Not Reported
Restasis	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807245	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598520		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Anakinra			C				Not Reported
	Ativan			C				Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			C				Not Reported

Codeine	C		Not Reported
Darifenacin	C		Not Reported
Darifenacin Hydrobromide	C		Not Reported
Desoximetasone	C		Not Reported
Dilaudid	C		Not Reported
Diphenhydramine Hydrochloride	C		Not Reported
Furosemide	C		Not Reported
Hydromorphone	C		Not Reported
Pantoloc [Pantoprazole]	C		Not Reported
Pantoprazole	C		Not Reported
Restasis	C		Not Reported
Rituximab	C	Intravenous drip	Not Reported
Synthroid	C		Not Reported
Trimethoprim	C		Not Reported
Urispas	C		Not Reported
Vagifem	C		Not Reported
Kadian	C		Not Reported
Kenalog [Triamcinolone Acetonide]	C		Not Reported
Lasix [Furosemide]	C		Not Reported
Loperamide	C		Not Reported
Morphine Sulfate	C		Not Reported
Norflex [Orphenadrine Citrate]	C		Not Reported
Omnaris	C		Not Reported
Oxyneo	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807267	EXPEDITED (15-DAY)		DE, HO	FR-TEVA-2020-FR-1237207		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Ventricular Extrasystoles	Nebivolol			S	Oral	5 Mg		Actavis
	Plaquenil			S	Oral	600 Mg		Not Reported
	Valsartan			C	Oral	160 Mg		Not Reported
	Augmentin			C	Oral	3 Gm		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807315	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597899		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807339	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598571		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation;	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methyl Salicylate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 6.0 Months		Not Reported

Injection Site Pruritus; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Pneumonia; Pruritus; Pulmonary Fibrosis; Rheumatoid Arthritis; Septic Shock; Synovitis; Treatment Failure; Urinary Tract Infection; Urosepsis	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Salicylates Nos	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807382	EXPEDITED (15-DAY)		HO	ES-ACCORD-182384		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Azithromycin			S	Oral	500 Mg Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807416	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598837		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Gait Disturbance; Inflammation; Mouth Ulceration; Pain;	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported

Peripheral Swelling; Rotator Cuff Syndrome; Swelling; Therapeutic Product Effect Decreased; Tongue Ulceration; Tooth Infection; Treatment Failure	Golimumab		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Indometacin		C		Not Reported
	Prednisone		C		Not Reported
	Tramadol		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807426	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598036			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807451	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1019154		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; Diarrhoea; Drug Ineffective; Joint Swelling;	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Migraine; No Adverse Event; Peripheral Swelling; Prescribed Underdose; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra	S	Unknown		Not Reported
	Anakinra	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown	7 Milligram Daily;	Not Reported
	Celebrex	S	Unknown		Not Reported
	Celebrex	S	Unknown		Not Reported
	Cimzia	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Remicade	S	Unknown	7 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Arava	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Prednisone	S	Unknown	7 Milligram Daily;	Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral	10 Milligram Daily;	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram Daily;	Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Acetaminophen/Codeine Phosphate	C	Unknown		Not Reported
	Altace	C	Unknown		Not Reported
	Altace	C	Unknown		Not Reported

Apo-Gabapentin	C	Oral		Not Reported
Apo-Gabapentin	C	Unknown		Not Reported
Apo-Gabapentin	C	Oral		Not Reported
Apo-Gabapentin	C	Unknown		Not Reported
Atorvastatin Calcium	C	Oral	40 Milligram Daily;	Not Reported
Atorvastatin Calcium	C	Unknown		Not Reported
Cipralex [Escitalopram]	C	Unknown		Not Reported
Citalopram Hydrobromide	C	Unknown		Not Reported
Cymbalta	C	Unknown	120 Milligram Daily;	Not Reported
Cymbalta	C	Unknown	120 Milligram Daily;	Not Reported
Cymbalta	C	Unknown		Not Reported
Escitalopram	C	Unknown		Not Reported
Estrace	C	Unknown		Not Reported
Hydrochlorothiazide	C	Unknown		Not Reported
Hydromorphone Hcl	C	Oral	6 Milligram Daily;	Not Reported
Mupirocin	C	Topical		Not Reported
Mupirocin	C	Topical		Not Reported
Pantoloc [Pantoprazole]	C			Not Reported
Tapentadol Hydrochloride	C	Unknown		Not Reported
Tramadol Hydrochloride	C	Oral		Not Reported
Tramacet	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807497	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598405		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Butterfly Rash; Condition Aggravated; Drug Ineffective; Epicondylitis; Malaise; Musculoskeletal Pain; Off	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Label Use; Systemic Lupus Erythematosus	Methotrexate	S	Parenteral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807531	EXPEDITED (15-DAY)		HO	CA-ROCHE-2598745		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807536	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598164			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807575	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236739			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported

Adalimumab	S	Subcutaneous	Not Reported
Arava	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Folic Acid	S	Unknown	Not Reported
Fosamax	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807725	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236726			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Tocilizumab	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807727	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20200503765			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Otezla			S	Unknown			Celgene
	Certolizumab Pegol			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Advair			C	Unknown			Not Reported
	Allopurinol			C	Unknown			Not Reported
	Atrovent Hfa			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Cyclobenzaprine Hydrochloride			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Esomeprazole Magnesium Hydrate			C	Unknown			Not Reported

	Hydromorphone Hydrochloride	C	Unknown	Not Reported
	Ibuprofen	C	Unknown	Not Reported
	Leucovorin Calcium	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Ventolin Hfa	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807730	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236781			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fibrosis; Ill-Defined Disorder; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Prednisone			S	Oral			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Humira			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807800	EXPEDITED (15-DAY)		LT	CA-ROCHE-2598497			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported

	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S			Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported
	Oxyquinoline Sulfate	S	Unknown		Not Reported
	Oxyquinoline Sulfate	S			Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807838	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597720		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use; Synovitis	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Methotrexate	S	Unknown	Not Reported
Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Estrogel	C	Unknown	Not Reported
Furosemide	C	Unknown	Not Reported
Morphine	C	Unknown	Not Reported
Potassium Chloride	C	Unknown	Not Reported
Valsartan	C	Unknown	Not Reported
Xalatan	C	Ophthalmic	Not Reported
Zingiber Officinale	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807840	EXPEDITED (15-DAY)		OT	ES-FRESENIUS KABI-FK202004826		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tinnitus	Midazolam (Manufacturer Unknown)			S	Unknown	Unk		Fresenius Medical Care
	Ceftriaxon (Manufacturer Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Mg/12 H		Not Reported
	Ritonavir/Lopinavir			S	Oral	5 Ml/ 12 H (80 Mg + 20 Mg) / Ml Oral Solution, 5 Bottles Of 60 Ml + 5 Syringes Of 5 Ml)		Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807858	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200406217		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Nausea; Rash; Therapeutic Product Effect Decreased	Levaquin	S	Unknown	Janssen
	Arava	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Cephalexin Monohydrate	S	Unknown	Not Reported
	Ciprofloxacin	S	Unknown	Not Reported
	Clindamycin	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Enalapril	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Hydralazine Hydrochloride	S	Unknown	Not Reported
	Hydrochlorothiazide	S	Unknown	Not Reported
	Losartan	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Metoprolol Tartrate	S	Unknown	Not Reported
	Moxifloxacin Hydrochloride	S	Unknown	Not Reported
	Pantoprazole Magnesium	S	Unknown	Not Reported
	Pariet	S	Unknown	Not Reported
	Penicillin /00000901/	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Prednisone	C		Not Reported
	Hydroxychloroquine Sulfate	C		Not Reported
	Iron Sucrose	C		Not Reported
	Esomeprazole	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807894	EXPEDITED (15-DAY)		OT	ES-ACCORD-182460		53 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Azithromycin			S	Oral	500 Mg Dia		Not Reported

	Roactemra	S	Intravenous (not otherwise specified)	600 Mg	Not Reported
	Enoxaparin	S	Subcutaneous	40 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807895	EXPEDITED (15-DAY)		HO	ES-ACCORD-182670		83 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hyponatraemia	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported
	Symbicort Turbuhaler			S	Respiratory (inhalation)	2-2-2, 160 Micrograms / 4.5 Micrograms / Inhalation Powder For Inhalation, 1 Inhaler Of 120 Doses		Not Reported
	Salbutamol			S	Respiratory (inhalation)	2-2-2 Inh		Not Reported
	Azithromycin			S	Oral	500 Mg Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807925	EXPEDITED (15-DAY)		DE, HO, LT	CA-ROCHE-2601473		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported

Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Arava	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S			Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S			Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported
	Xeljanz	S	Oral		Not Reported
	Minocycline Hydrochloride	S	Unknown		Not Reported
	Cannabis Sativa	S	Unknown		Not Reported
	Ilaris	S	Subcutaneous	Single-Use Vial	Not Reported
	Oxycodone	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Rituximab	C	Unknown		Not Reported
	Lyrica	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807933	EXPEDITED (15-DAY)		HO	NVSC2020ES129940		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Bid		Novartis
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid (For 5-10 Days)		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807960	EXPEDITED (15-DAY)		OT	DK-PFIZER INC-2020197070		50 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Feet Syndrome; Dry Mouth; Intervertebral Disc Protrusion; Neuropathy Peripheral; Osteopenia; Pain In Extremity; Small Fibre Neuropathy	Methotrexate			S		15 Mg, Weekly		Pfizer
	Methotrexate			S		20 Mg, Weekly		Pfizer
	Methotrexate			S		25 Mg, Weekly		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Prednisolone			C	Oral	12.5 Mg, Daily		Not Reported
	Prednisolone			C	Oral	Dose Reduced		Not Reported
	Prednisolone			C	Oral	5 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808058	EXPEDITED (15-DAY)		DE, HO	ES-PFIZER INC-2020198873		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Hypofibrinogenaemia; Upper Gastrointestinal Haemorrhage	Meropenem			S	Intravenous (not otherwise specified)	1 G, 3x/Day (Every 8 Hours)		Pfizer
	Linezolid			S	Intravenous (not otherwise specified)	600 Mg, 2x/Day (Every 12 Hours)		Pfizer
	Roactemra			S		600 Mg, Single		Not Reported
	Roactemra			S				Not Reported
	Piperacillin/Tazobactam			S	Intravenous (not otherwise specified)	1 Df, 3x/Day (Every 8 Hours)		Not Reported
	Metamizole			S	Intravenous (not otherwise specified)	2 G, 3x/Day (2 G Every 8 Hours)		Not Reported

	Hydroxychloroquine		S	Oral	400 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808093	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598666			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Off Label Use; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S	Oral			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mirtazapine			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808150	EXPEDITED (15-DAY)		OT	NVSC2020ES129943		65 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Therapeutic; Gastrointestinal Disorder; Product Use In Unapproved Indication; Renal Failure	Lopinavir,Ritonavir			S	Unknown	200/100 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Bid		Novartis
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid (For 5-10 Days)		Novartis
	Tacrolimus			S	Unknown	Unk		Not Reported
	Tacrolimus			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808183	EXPEDITED (15-DAY)		DS	CA-ROCHE-2598082		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Cortisone Acetate			S	Oral			Not Reported
	Topicort [Desoximetasone]			S	Oral			Not Reported
	Topicort [Desoximetasone]			S	Cutaneous			Not Reported
	Topicort [Desoximetasone]			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydrocortisone Acetate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral	11.0 Years		Not Reported
	Methotrexate Sodium			S	Oral			Not Reported

Orencia	S	Intravenous (not otherwise specified)			Not Reported
Orencia	S	Subcutaneous			Not Reported
Paracetamol	S	Unknown			Not Reported
Phthalylsulfathiazole	S	Subcutaneous			Not Reported
Prednisone	S	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported
Rituxan	S	Intravenous (not otherwise specified)	365.0		Not Reported
Sarilumab	S	Unknown			Not Reported
Simponi	S	Subcutaneous			Not Reported
Stelara	S	Unknown			Not Reported
Sulfasalazine	S	Subcutaneous			Not Reported
Sulfasalazine	S	Oral	365.0		Not Reported
Sulfasalazine	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Xeljanz	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808262	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600334			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Off Label Use; Oral Discomfort; Treatment Failure	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Sarilumab	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Tofacitinib	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808273	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597830		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Ill-Defined Disorder; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Off Label Use; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Toradol			S	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808302	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598106			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Therapy Duration: 577		Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown	Therapy Duration: 577		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 577		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 5 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 577		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral	Therapy Duration: 577		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 577		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 577		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 577		Not Reported
	Orencia			S	Unknown	Therapy Duration: 577		Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Therapy Duration: 577		Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 577	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous	Therapy Duration: 577	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808320	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599535		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808362	EXPEDITED (15-DAY)		OT	NVSC2020IL137300		43 YR	Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Product Use In Unapproved Indication; Retinal Injury	Methotrexate			S	Unknown	20 Mg, Qw		Novartis
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Azathioprine			C	Unknown	3 Mg/Kg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808452	EXPEDITED (15-DAY)		HO	CA-ROCHE-2599352			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Hypersensitivity; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Simponi	C		Not Reported
	Xeljanz	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808581	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236786			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

	Plaquenil[Hydroxychloroquine Phosphate]]	S		400 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Tofacitinib Citrate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808608	EXPEDITED (15-DAY)		DE	ES-PFIZER INC-2020198882		26 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Mg, 1x/Day		Not Reported
	Enoxaparin			S	Subcutaneous	40 Mg, 1x/Day		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Single		Not Reported
	Tocilizumab			S				Not Reported
	Dexketoprofen			S	Intravenous (not otherwise specified)	25 Mg, 3x/Day (Every 8 Hours)		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808609	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020198940		59 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use In Unapproved Indication; Product Use Issue; Supraventricular Tachycardia	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808668	EXPEDITED (15-DAY)		OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2020VAL000390			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hepatocellular Injury; Off Label Use	Cefotaxime Sodium			S	Intravenous (not otherwise specified)	Unk		Validus
	Plaquenil /00072603/			S	Oral	Unk		Not Reported
	Plaquenil /00072603/			S				Not Reported
	Rovamycine /00074401/			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Paracetamol			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Linezolide Kabi			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Movicolon			C		Unk		Not Reported
	Amikacine /00391002/			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808728	EXPEDITED (15-DAY)		HO, OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2020VAL000391			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Off Label Use; Purpura; Thrombocytopenia	Cefotaxime Sodium			S	Intravenous (not otherwise specified)	Unk		Validus
	Plaquenil /00072603/			S	Oral	Unk		Not Reported
	Plaquenil /00072603/			S				Not Reported
	Azithromycin			S	Oral	Unk		Not Reported
	Esomeprazole Magnesium			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Lovenox			S	Subcutaneous	Unk		Not Reported

	Noradrenaline /00127501/	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Loxen /00639802/	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Nimbex /01302502/	C		Unk	Not Reported
	Sufentanil	C		Unk	Not Reported
	Hypnovel /00634103/	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808802	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236733			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17808803	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236789		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S				Barr
	Prednisone			S	Unknown			Actavis
	Alendronate Sodium			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Diclofenac	C	Unknown	Not Reported
	Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17809219	EXPEDITED (15-DAY)		OT	CA-SA-2018SA288283		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Hypersensitivity; Drug Ineffective; Hypersensitivity; Insomnia; Loss Of Personal Independence In Daily Activities; Pain; Rheumatoid Arthritis; Stress At Work; Swelling	Arava			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Plaquenil Sulfate			S	Unknown			Sanofi
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			C	Unknown			Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown			Not Reported
	Cimzia			C				Not Reported
	Humira			C	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported

	Lyrica	C	Unknown	Unk		Not Reported
	Arthrotec	C	Unknown			Not Reported
	Tylenol [Paracetamol]	C	Unknown	Unk		Not Reported
	Rabeprazole	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17809246	EXPEDITED (15-DAY)		OT	CA-SA-2019SA058842		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Injury; Swelling	Hydroxychloroquine			S				Sanofi
	Methotrexate			S				Not Reported
	Leflunomide			S				Sanofi
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17810378	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3409473-00			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ageusia; Anosmia; Blindness; Blood Lactate Dehydrogenase Abnormal; Diarrhoea; Fatigue; Gamma-Glutamyltransferase Abnormal; Hypoacusis; Malaise; Nervousness; Off Label Use	Kaletra			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17810521	EXPEDITED (15-DAY)		OT	CA-ROCHE-1857550			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Nausea	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Intramuscular	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17811001	DIRECT	Y	HO			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	11457282	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-1626689			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Independence In Daily Activities; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Nail Disorder; Nail Operation; Onychomadesis; Onychomycosis	Cimzia	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Solution	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Infliximab	S	Unknown		Not Reported
	Infliximab	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Arava	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	11631404	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1643958			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Asthenia; Condition Aggravated; Contraindicated Product Administered; Cough; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fatigue; Fine Motor Skill Dysfunction; Goitre; Headache; Inflammation; Joint Swelling; Lower Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Thyroid Disorder	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Ketoprofen	C	Unknown	Not Reported
	Losec [Omeprazole]	C		Not Reported
	Citalopram Hydrobromide	C		Not Reported
	Crestor	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Rosuvastatin Calcium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	12130379	EXPEDITED (15-DAY)		OT	CA-ROCHE-1717281			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Intentional Product Use Issue; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Onychoclasis; Synovitis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Zostavax			S	Unknown			Not Reported

	Zostavax	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Cortisone	C	Oral	Not Reported
	Voltaren [Diclofenac]	C	Unknown	Not Reported
	Cortisone Acetate	C	Subcutaneous	Not Reported
	Desoximetasone	C	Subcutaneous	Not Reported
	Desoximetasone	C	Oral	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Desoximetasone	C	Oral	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Diclofenac	C	Oral	Not Reported
	Diclofenac	C	Oral	Not Reported
	Diclofenac	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	12909635	EXPEDITED (15-DAY)		OT	CA-ROCHE-1564010		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Pain; Skin Reaction; Skin Swelling; Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	12974904	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-1859498		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Bupropion			C				Not Reported
	Esomeprazole			C				Not Reported
	Folic Acid			C				Not Reported
	Levothyroxine			C				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	13091577	EXPEDITED (15-DAY)		OT	CA-ROCHE-1875078		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Off Label Use;	Rituxan			S	Unknown	Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Methotrexate Sodium		S	Subcutaneous		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Gold		S	Unknown		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Methotrexate		S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	13100775	EXPEDITED (15-DAY)		OT	CA-ROCHE-1877150			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Sinusitis; Stomatitis;	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	08/--/2002 To 05/--/2005		Not Reported

Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure; Treatment Failure; Weight Decreased	Enbrel	S	Unknown	Duration 730 Days	Not Reported
	Arava	S	Oral	Dose And Frequency Unknown.	Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cimzia	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	Dose And Frequency Unknown.	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Imuran [Azathioprine]	S	Unknown	Dose And Frequency Unknown	Not Reported
	Sulfasalazine	S	Unknown	Dose And Frequency Unknown.	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ciclosporin	S	Oral	Dose And Frequency Unknown.	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)		Not Reported

Methotrexate	S	Oral		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Dose And Frequency Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Certolizumab	S	Unknown		Not Reported
Certolizumab	S	Unknown		Not Reported
Certolizumab	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown	Dose And Frequency Unknown.	Not Reported
Cyclosporine	S	Oral	Dose And Frequency Unknown	Not Reported
Cyclosporine	S	Unknown		Not Reported
Cyclosporine	S	Oral		Not Reported
Cyclosporine	S	Unknown		Not Reported
Methotrexate Sodium	S	Unknown	Dose And Frequency Unknown.	Not Reported
Azathioprine	S	Unknown	Dose And Frequency Unknown.	Not Reported
Lyrica	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Simponi	S	Unknown		Not Reported
Apo-Azathioprine	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Gold	S	Unknown		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported

	Sodium Aurothiomalate	S	Unknown		Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous		Not Reported
	Prednisone	C			Not Reported
	Piroxicam	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	13166185	EXPEDITED (15-DAY)		OT	CA-ROCHE-1886967		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	13213527	EXPEDITED (15-DAY)		OT	CA-SA-2015SA178531		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthritis; Condition Aggravated; Drug Ineffective; Drug Ineffective; Drug Ineffective; Menopausal	Plaquenil			S	Oral	400 Mg,Qd		Sanofi
	Leflunomide			S	Unknown	20 Mg,Qd		Sanofi
	Methotrexate			S	Oral	10 Mg,Qw		Not Reported
	Methotrexate			S	Oral	20 Mg,Qw		Not Reported

Symptoms; Musculoskeletal Stiffness; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate	S	Unknown	Unk Unk,Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg,Unk	Not Reported
	Enbrel	S	Unknown	Unk Unk,Unk	Not Reported
	Enbrel	S	Unknown	1 Df,Unk	Not Reported
	Mefenamic Acid	S	Unknown	400 Mg,Bid	Not Reported
	Xeljanz	S	Unknown	Unk Unk,Unk	Not Reported
	Xeljanz	S	Unknown	Unk Unk,Unk	Not Reported
	Xeljanz	S	Unknown	5 Mg,Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	14287715	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2035078		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sciatica; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Altace			S	Unknown	1 Unit Not Reported		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Cosopt			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Levothyroxine Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Folic Acid	C	Unknown	Not Reported
	Levothyroxine	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	14831436	EXPEDITED (15-DAY)		OT	CA-ROCHE-2112282		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous	Therapy Duration: 8 Years		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 8 Years		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Meloxicam			C	Oral			Not Reported

	Prednisolone	C			Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	15327981	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175377		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arthrotec			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Imuran [Azathioprine]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	15674323	EXPEDITED (15-DAY)		OT	US-ASTELLAS-2018US050584			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphopenia; Premature Baby	Tacrolimus			S	Transplacental	Unk, Unknown Freq.		Astellas
	Hydroxychloroquine			S	Transplacental	Unk Unk, Unknown Freq.		Not Reported
	Azathioprine			S	Transplacental	Unk Unk, Unknown Freq.		Not Reported
	Prednisone			S	Transplacental	Unk Unk, Unknown Freq.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	15843598	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190118854		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arthrotec			C	Oral			Not Reported

	Gold	C	Unknown		Not Reported
	Imuran	C	Unknown		Not Reported
	Vitamin D	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	15929079	EXPEDITED (15-DAY)		OT	CA-ROCHE-1832232		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	16318010	EXPEDITED (15-DAY)		HO	EC-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-207974		14 YR	Female	ECU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Posterior Reversible Encephalopathy Syndrome	Atorvastatin			S	Unknown	10 Milligram		Sun
	Atorvastatin			S				Sun
	Enalapril			S	Unknown	5 Milligram		Ranbaxy
	Enalapril			S				Ranbaxy
	Furosemide			S	Unknown	40 Milligram		Sun
	Furosemide			S				Sun
	Hydroxychloroquine			S	Unknown	200 Milligram		Ipca
	Hydroxychloroquine			S				Ipca
	Prednisone			S	Unknown	30 Milligram		Mutual
	Prednisone			S				Mutual

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	16646741	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202691			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine Sulfate			S		200 Mg, Biw		Sanofi
	Hydroxychloroquine Sulfate			S		400 Mg, Tiw		Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Sulfasalazine			S				Not Reported
	Actemra			S	Subcutaneous	162 Mg, Qow		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Qow		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Orencia			S		Unk		Not Reported
	Prednisone			C		20 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	16770849	EXPEDITED (15-DAY)		OT	DE-TEVA-2019-DE-1100415			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Omeprazole			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Actavis
	Omeprazole			S	Oral	40 Milligram Daily; 20 Mg, Bid		Actavis
	Ramipril			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Actavis
	Ramipril			S		5 Milligram Daily;		Actavis
	Sildenafil Citrate			S	Unknown	60 Milligram Daily;		Actavis
	Volibris			S	Oral	30 Milligram Daily;		Not Reported
	Volibris			S	Oral	1 Dosage Forms Daily;		Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qwk		Not Reported
	Roactemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported
	Spasmolyt			S	Unknown	1 Df, Qd; 1 Number Of Units In The Interval: 1 Definition Of The Interval: Day		Not Reported
	Spasmolyt			S	Unknown	30 Mg, Qd; Number Of Separate Dosages: 1 Number Of Units In The Interval: 1 Definition Of The Interv		Not Reported
	Spasmolyt			S	Unknown	15 Milligram Daily;		Not Reported
	Spasmolyt			S	Unknown	30 Milligram Daily;		Not Reported
	Quensyl			S	Unknown	80 Milligram Daily; 40 Mg, Bid		Not Reported
	Quensyl			S	Unknown	40 Milligram Daily; 20 Mg, Bid		Not Reported
	Ambrisentan			S	Oral	1 Dosage Forms Daily;		Not Reported
	Ambrisentan			S	Unknown	30 Milligram Daily;		Not Reported

	Lyrica	S	Unknown	100 Milligram, Tid	Not Reported
	Lyrica	S	Unknown	1 Df, Tid (1 Df, 3x/Day (1 - 1- 1)	Not Reported
	Apixaban	S	Unknown	10 Milligram Daily; 2.5 Milligram, Bid	Not Reported
	Apixaban	S	Unknown	2 Dosage Forms Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	16906561	EXPEDITED (15-DAY)		HO	CA-ROCHE-2425931		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Hip Arthroplasty; Infection; Knee Arthroplasty; Off Label Use; Seronegative Arthritis; Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Rituxan			S	Intravenous drip			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Naprosyn [Naproxen]			C	Unknown			Not Reported
	Erythromycin			C				Not Reported
	Morphine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17012579	EXPEDITED (15-DAY)		DS	CA-ROCHE-2458308			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy;	Actemra			S	Unknown			Not Reported

Contraindicated Product Administered; Drug Ineffective; Liver Function Test Increased; Therapeutic Product Effect Decreased	Actemra	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Imuran [Azathioprine]	C	Unknown	Not Reported
	Azathioprine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17250075	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516466			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Incorrect Route Of Product Administration; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect	Tocilizumab			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Decreased; Treatment Failure	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rabeprazole Sodium	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17371160	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2538246		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Off Label Use; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17386806	EXPEDITED (15-DAY)		DS, HO, OT	CA-CELGENEUS-CAN-20200111049		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Otezla			S	Oral	120 Milligram		Celgene
	Otezla			S				Celgene
	Otezla			S				Celgene
	Alendronate Sodium			S	Unknown	70 Milligram		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	7.1429 Milligram		Not Reported
	Enbrel			S	Subcutaneous	7.1429 Milligram		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ibuprofen			S	Oral	600 Milligram		Not Reported
	Ibuprofen			S	Oral			Not Reported
	Infliximab			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown	12.5 Milligram		Not Reported
	Methotrexate			S	Unknown	.1096 Milligram		Not Reported
	Methotrexate			S	Unknown	.1315 Milligram		Not Reported
	Methotrexate			S	Unknown	17.5 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	70 Milligram		Not Reported
	Orencia			S	Subcutaneous			Not Reported

Orencia	S	Unknown		Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Sulfasalazine	S	Endocervical		Not Reported
Stelara	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous		Not Reported
Rituxan	S	Intravenous drip	2000 Milligram	Not Reported
Remicade	S	Intravenous drip		Not Reported
Benadryl	S	Unknown		Not Reported
Mogadon	C	Oral	5 Milligram	Not Reported
Colchicine	C	Unknown		Not Reported
Nitrazepam	C	Oral	5 Milligram	Not Reported
Dexilant	C	Oral		Not Reported
Febuxostat	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Gravol	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported
Uloric	C	Oral	160 Milligram	Not Reported
Oxycodone	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17395477	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542443		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Bone Disorder; Condition Aggravated; Contraindicated Product Administered; Drug	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Hypersensitivity; Drug Ineffective; Finger Deformity; Off Label Use; Pain; Peripheral Swelling; Rash; Swelling; Tendon Disorder; Tenosynovitis; Treatment Failure; Urticaria	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Penicillin G Sodium	S	Unknown	Not Reported
	Penicillin V Potassium	S	Unknown	Not Reported
	Rocuronium	S	Unknown	Not Reported
	Rocuronium Bromide	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17460784	EXPEDITED (15-DAY)		OT	CA-ROCHE-2554332			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Limb Deformity; Musculoskeletal Pain; Pain; Pain In Extremity; Pruritus; Rash; Squamous	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Cell Carcinoma; Treatment Failure	Hydroxychloroquine		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Methotrexate		S	Oral		Not Reported
	Methotrexate		S	Oral		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Azathioprine Sodium		S	Unknown		Not Reported
	Imuran [Azathioprine]		S	Unknown		Not Reported
	Neoral		S	Unknown		Not Reported
	Citalopram Hydrobromide		C	Unknown		Not Reported
	Citalopram Hydrobromide		C	Unknown		Not Reported
	Citalopram Hydrobromide		C	Unknown	1.0 Dosage Forms	Not Reported
	Prednisone		C	Unknown		Not Reported
	Prednisone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17570483	EXPEDITED (15-DAY)		OT	CA-ROCHE-2570439		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Minocycline	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17579775	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327856		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthropathy; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Knee Arthroplasty; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Musculoskeletal Disorder; Skin Warm; Spinal Stenosis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Gold			C				Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Prednisone			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17605656	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332784		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; No Adverse Event; Off Label Use; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Neoral			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Endocervical			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	C	Oral	And Xeljanz Xr (Prolonged Release)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17702479	EXPEDITED (15-DAY)		OT	AU-ABBVIE-20K-008-3373197-00			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Ageusia; Arthralgia; Depression; Dna Antibody Negative; Drug Interaction; Fibromyalgia; Gait Disturbance; Liver Function Test Abnormal; Migraine; Nausea; Panic Attack; Paraesthesia; Psoriasis; Psoriatic Arthropathy; Respiratory Syncytial Virus Infection; Sleep Disorder; Suicidal Ideation; Systemic Lupus Erythematosus; Tachyarrhythmia; Type 1 Diabetes Mellitus; Urinary Tract Infection; Viral Tonsillitis	Humira			S	Subcutaneous			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Sildenafil			S	Oral			Not Reported
	Glyceryl Trinitrate			S	Oral			Not Reported
	Prasugrel			S	Unknown			Not Reported
	Novorapid			S	Subcutaneous			Not Reported
	Topiramate			S	Unknown			Not Reported
	Glucagen			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Reboxetine			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported
	Rosuvastatin Calcium			S	Unknown			Not Reported

	Ezetimibe	S	Unknown	Not Reported
	Aspirin	S	Unknown	Not Reported
	Ramipril	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Endone	S	Unknown	Not Reported
	Ivabradine	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Prednisolone	S	Unknown	Not Reported
	Cholecalciferol	S	Unknown	Not Reported
	5-Methyltetrahydrofolate	S	Unknown	Not Reported
	Cannabis Sativa Oil	S	Unknown	Not Reported
	Mirena	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17742017	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-020078		57 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Intentional Product Use Issue; Pyrexia	Amoxicillin			S	Oral	3 Gram, Once A Day		Aurobindo
	Hydroxychloroquine Sulfate			S	Oral	800 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17743899	EXPEDITED (15-DAY)		HO	CA-ROCHE-2589699		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Rheumatoid Arthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported

Methotrexate	S	Oral	Not Reported
Orencia	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Rituxan	S	Intravenous drip	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Meloxicam	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17747147	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200436816			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hand Deformity; Hip Arthroplasty; Impaired Work Ability; Joint Swelling; Knee Arthroplasty; Polyarthritis; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Indometacin			S	Oral			Not Reported
	Indometacin			S	Oral			Not Reported
	Indometacin			S	Oral			Not Reported
	Indometacin			S	Oral			Not Reported

Indometacin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17767661	EXPEDITED (15-DAY)		DE, OT	FR-PFIZER INC-2020180079			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17772547	EXPEDITED (15-DAY)		OT	ES-FRESENIUS KABI-FK202004490		78 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Long Qt Syndrome	Midazolam (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Midazolam (Manufacturer Unknown)			S				Fresenius Medical Care
	Propofol (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Propofol (Manufacturer Unknown)			S				Fresenius Medical Care
	Ceftriaxon (Manufacturer Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Ritonavir/Lopinavir			S	Oral			Not Reported
	Zea Mays Extract			C	Unknown			Not Reported
	Formoterol Fumarate/Budesonide			C	Unknown			Not Reported
	Tamsulosin Hydrochloride			C	Unknown			Not Reported
	Simvastatin			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Hydrocortisone Acetate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17773513	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-246919		96 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Extrasystoles; Off Label Use	Azithromycin			S	Unknown	500 Milligrams, Daily, Tablet		Sun
	Plaquenil			S	Unknown	400 Milligrams, Daily		Not Reported
	Lasix 25 Mg Compresse			C	Unknown	25 Milligrams, Daily		Not Reported
	Novorapid			C	Unknown	Unk		Not Reported
	Normix			C	Unknown	Unk		Not Reported
	Dobetin			C	Unknown	Unk		Not Reported
	Lantus			C	Unknown	Unk		Not Reported
	Movicol			C	Unknown	Unk		Not Reported
	Deltacortene 25 Mg Compresse			C	Unknown	Unk		Not Reported
	Pantorc 20 Mg Compresse Gastroresistenti			C	Unknown	20 Milligrams, Daily		Not Reported
	Cardirene 75 Mg			C	Unknown	75 Milligrams, Daily		Not Reported
	Metoprololo			C	Unknown	50 Milligrams, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17801314	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247202		78 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Long Qt Syndrome	Midazolam			S	Unknown	Unk		Sun
	Midazolam			S				Sun
	Azithromycin			S	Unknown	Unk		Sun
	Propofol			S	Unknown	Unk		Not Reported
	Propofol			S				Not Reported

	Dolquine 200 Mg Comprimidos Recubiertos	S	Oral	200 Milligram, Bid	Not Reported
	Kaletra	S	Oral	Unk	Not Reported
	Ceftriaxona (501a)	S	Unknown	Unk	Not Reported
	Omnic Ocas 0,4 Mg Comprimidos De Liberacion Prolongada Recubiertos ...	C	Unknown	Unk	Not Reported
	Cortic - Corticoide	C	Unknown	Unk	Not Reported
	Manidon Hta 240 Mg Comprimidos De Liberacion Prolongada, 30 Comprim...	C	Unknown	Unk	Not Reported
	Rilast Turbuhaler 160 Microgramos/4,5 Microgramos/Inhalacion Polvo...	C	Unknown	Unk	Not Reported
	Simvastatina 20 Mg 28 Comprimidos	C	Unknown	Unk	Not Reported
	Kalpress 160 Mg Comprimidos Recubiertos Con Pelicula, 28 Comprimido...	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17804027	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1235537		43 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Behaviour Disorder	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809266	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-025598		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Thrombocytopenia	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Roactemra			S	Intravenous (not otherwise specified)	600 Milligram, Once A Day		Not Reported
	Enoxaparin			S	Subcutaneous	80 Milligram, Two Times A Day		Not Reported

	Hydroxychloroquine		S	Oral	400 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809432	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247759		49 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Sun
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Mg Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809442	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-025271		61 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Amoxicillin			S	Oral	3 Gram		Aurobindo
	Clavulanic Acid			S	Oral	600 Milligram		Not Reported
	Plaquenil			S	Oral	600 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809472	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-019736		75 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S				Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809535	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599814		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Headache; Joint Swelling; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Tremor; Vitamin D Deficiency	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Amlodipine Besilate			S	Oral			Not Reported
	Asacol			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Bisoprolol Fumarate			C				Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported
	Ferrous Gluconate			C				Not Reported
	Folic Acid			C				Not Reported
	Pantoprazole Magnesium			C				Not Reported
	Tenofovir Disoproxil Fumarate			C				Not Reported
	Tylenol			C				Not Reported
	Vitamin D3			C				Not Reported
	Xeljanz			C				Not Reported
	Zopiclone			C				Not Reported
	Atacand Plus			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809571	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599460		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Rituximab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Amoxicillin Sodium;Clavulanate Potassium			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Amoxicillin;Clavulanate Potassium			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tridural			C	Unknown			Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809623	EXPEDITED (15-DAY)		OT	HR-ADVANZ PHARMA-GSH201801-000311			Unknown	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Muscular Weakness; Phospholipidosis; Proteinuria; Renal Disorder; Renal Impairment; Toxicity To Various Agents	Hydroxychloroquine		S	Unknown	500 Mg, Qd, Tablet	Concordia
	Azathioprine		C		50 Mg, Bid	Not Reported
	Prednisolone		C		10 Mg, Qd	Not Reported
	Levothyroxine		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809624	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599977			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Extremity Contracture; Joint Swelling; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Synovitis; Vomiting	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Synthroid			C				Not Reported
	Cymbalta			C				Not Reported

	Hydromorphone			C						Not Reported
	Remicade			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809640	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599612		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809723	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601836		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation; Off Label Use; Pneumonia; Pruritus; Rheumatoid Arthritis; Urosepsis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methyl Salicylate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)		
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809833	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247680		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Purpura; Thrombocytopenia	Azithromycin			S	Oral	Unk		Sun
	Noradrenaline			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cefotaxime Base			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Inexium			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Lovenox			S	Subcutaneous	Unk		Not Reported
	Loxen (Nicardipine Chlorhydrate)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Hypnovel			C	Unknown	Unk		Not Reported
	Sufentanil			C	Unknown	Unk		Not Reported
	Nimbex			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809969	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599524			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased;	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Pneumonia	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809981	EXPEDITED (15-DAY)		OT	ES-ACCORD-182511		45 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Enoxaparin			S	Subcutaneous	40 Mg Day		Not Reported
	Azithromycin			S	Oral	500 Mg Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809997	EXPEDITED (15-DAY)		HO	CA-ROCHE-2601414			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Hypersensitivity; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S		Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810098	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599567		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Drug Ineffective; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Adalimumab			S	Unknown	Therapy Duration: 9.0 Years		Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 05		Not Reported

				Years	
	Humira	S	Subcutaneous	Therapy Duration: 09 Years	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Therapy Duration: 15 Years	Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810101	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598069			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

	Prednisone		S	Oral	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810102	EXPEDITED (15-DAY)		HO	CA-ROCHE-2599579		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Ineffective; Fatigue; Loose Body In Joint; Off Label Use; Osteoporotic Fracture; Pain; Synovitis	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	2.0 Dosage Form		Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810198	EXPEDITED (15-DAY)		HO	CA-ROCHE-2598368			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Naproxen			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not			Not Reported

Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting			otherwise specified)	
	Infliximab	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Not Reported
	Immunoglobulins [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810199	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005434			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810200	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005435			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Electrocardiogram Qt Prolonged; Ventricular Fibrillation	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810305	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247893		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg ; In Total		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810415	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598506		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810508	EXPEDITED (15-DAY)		OT	CA-ROCHE-1962205			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Inflammation;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Treatment Failure	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Gold Sodium Thiomalate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810519	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-024941		48 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tachycardia	Amlodipine+Valsartan Film-Coated Tablet			S	Oral	Unk		Aurobindo
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810579	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598008		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported

Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S		Not Reported
	Desoximetasone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810580	EXPEDITED (15-DAY)		DE, HO, LT	CA-ROCHE-2601602		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use;	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Cannabis Sativa			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Enbrel	S		Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Minocycline	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Xeljanz	S	Oral	Not Reported
	Rituximab	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810597	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599648			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Off Label Use; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral	6.0 Years		Not Reported
	Leflunomide			S	Intramuscular			Not Reported
	Leflunomide			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			S	Unknown	Not Specified		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	4.0 Years		Not Reported
	Orencia			S	Oral	6.0 Years		Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Oral	6.O Years		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Ramipril			C	Unknown	Not Specified		Not Reported
	Vitamin D3			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported

	Ergocalciferol	C	Unknown		Not Reported
	Insulin	C	Unknown		Not Reported
	Lantus	C	Subcutaneous		Not Reported
	Lozide [Indapamide]	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810677	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600210		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product Administration; Liver Function Test Increased; Rash; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C				Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810690	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602929			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Condition Aggravated; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Off Label Use; Rheumatoid Arthritis; Somnolence; Visual Impairment	Acetaminophen	S	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Synthroid	C		Not Reported
	Xeljanz	C		Not Reported
	Meloxicam	C	Unknown	Not Reported
	Acetaminophen And Codeine Phosphate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810709	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598248			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis;	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Xeljanz	S	Oral	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C	Unknown	Not Reported
	Baclofen	C	Unknown	Not Reported
	Calcium	C	Unknown	Not Reported
	Calcium Gluconate	C	Unknown	Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Estradiol	C	Unknown	Not Reported
	Estrogel	C	Unknown	Not Reported
	Furosemide	C	Unknown	Not Reported
	Gravol	C		Not Reported
	Levaquin	C	Unknown	Not Reported
	Morphine	C		Not Reported
	Potassium Chloride	C	Unknown	Not Reported
	Valsartan	C	Unknown	Not Reported
	Xalatan	C	Ophthalmic	Not Reported
	Zingiber Officinale	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810788	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599751			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Off Label Use; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Phosphate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Rectal Gel		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Naproxen			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810800	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599770		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Visual Impairment	Actemra	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Leflunomide	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Methylprednisolone Acetate	C			Not Reported
	Prednisone	C			Not Reported
	Sulfasalazine	C	Oral		Not Reported
	Tylenol	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810817	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599854		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthritis; Burning Sensation; Contraindicated Product Administered; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Subcutaneous	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Adalimumab	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Kevzara	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported

	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Rabeprazole Sodium	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810820	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599662			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Off Label Use; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydrocortisone Acetate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810842	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600284		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Headache; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Tremor	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

Methotrexate	S	Oral		Not Reported
Adalimumab	S	Unknown		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810846	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600648			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Headache; Hypersensitivity Vasculitis; Hypertension; Musculoskeletal Stiffness; Nausea; Off Label Use; Rash; Respiratory Tract Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810898	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600537		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder;	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Methotrexate	S	Unknown	7.0 Years		Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	3.0 Years		Not Reported
	Sulfasalazine	S	Unknown	3.0 Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810909	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599531		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

Plaquenil [Hydroxychloroquine Sulfate]	S	Subcutaneous			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	S	Oral			Not Reported
Actemra	S	Intravenous (not otherwise specified)	8mg/Kg		Not Reported
Rituximab	S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810910	EXPEDITED (15-DAY)		OT	US-SA-2020SA128509			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Systemic Lupus Erythematosus	Dupixent			S	Unknown	Unk		Sanofi
	Plaquenil			S				Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810941	EXPEDITED (15-DAY)		DS	CA-ROCHE-2600279		9 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Injection Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Therapy Duration: 01 Month		Not Reported
	Rituximab			S				Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S				Not Reported
	Adalimumab			S	Subcutaneous	Therapy Duration: 4 Years		Not Reported
	Adalimumab			S				Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 609 Days		Not Reported
	Enbrel			S				Not Reported
	Etanercept			S	Subcutaneous			Not Reported

Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Dispensing Error; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Humira	S	Subcutaneous	Frequency: Cyclical	Not Reported
	Infliximab	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Therapy Duration: 2.0 Months	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	Therapy Duration: 5.0 Years	Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Abatacept	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810974	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601296		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Hereditary Angioedema; Infection; Intentional Product Use Issue; Joint Swelling; Liver Function Test Abnormal; Liver	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	3.0 Months		Not Reported
	Humira			S	Subcutaneous	3.0 Months		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	638.0	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral	7.0 Days	Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prevacid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810976	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2598434		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported

Positive; Intentional Product Use Issue; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Apo-Naproxen	S	Unknown	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Immunoglobulins [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)	Not Reported
	Immunoglobulins [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Unknown	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Not Reported
	Triamcinolone Hexacetonide	S	Other	Not Reported
	Naproxen	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810997	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601428			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthma; Drug Ineffective; Encephalitis Viral; Infection; Lung Disorder; Retinal Deposits; Wheezing	Rituximab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17811009	EXPEDITED (15-DAY)		HO	CA-ROCHE-2601514		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Daily Activities; Panniculitis; Peripheral Swelling; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Ciclosporin	C		Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17811046	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599637		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rosuvastatin			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17811141	EXPEDITED (15-DAY)		OT	ES-ACCORD-182600		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatitis; Off Label Use	Hydroxychloroquine		S	Oral	400 Mg Day	Not Reported
	Azithromycin		S	Oral	500 Mg Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17811170	EXPEDITED (15-DAY)		HO	CA-ROCHE-2601669		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Synovitis; Thrombocytopenia; White Blood Cell Count Decreased	Rituximab			S	Intravenous drip			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			C	Subcutaneous			Not Reported
	Advil [Ibuprofen]			C				Not Reported
	Arava			C	Oral			Not Reported
	Folic Acid			C				Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Ketorolac			C				Not Reported
	Naproxen			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17811317	EXPEDITED (15-DAY)		HO	ES-ACCORD-182419		48 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatitis	Hydroxychloroquine	S	Oral	400 Mg Day		Not Reported
	Azithromycin	S	Oral	500 Mg Day		Not Reported
	Colchicine	S	Oral	1 U Breakfast		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17811320	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599199		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cerebrovascular Accident; Diverticular Perforation; Drug Hypersensitivity; Drug Intolerance; Insomnia; Joint Swelling; Knee Arthroplasty; Pain; Peripheral Swelling; Psoriasis; Psoriatic Arthropathy; Rash; Skin Reaction; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Calcium			S	Unknown			Not Reported
	Fosinopril			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Morphine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Synthroid			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17811632	EXPEDITED (15-DAY)		OT	GB-ACCORD-182513		53 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Nausea	Hydroxychloroquine			S				Not Reported
	Colecalciferol			C		(Not Low Vit D)		Not Reported
	Fluoxetine			C				Not Reported

	Levothyroxine	C	Not Reported
	Cerazette	C	Not Reported
	Hydroxychloroquine Sulfate	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17811798	EXPEDITED (15-DAY)		HO	CA-ROCHE-2599045			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Localised Infection; Malaise; Pleurisy; Pneumonia	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17811825	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238636			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Epistaxis; Headache; Insomnia; Nausea; Osteonecrosis Of Jaw; Transaminases Increased	Risedronate Sodium			S	Oral			Teva
	Mycophenolate Mofetil			S	Oral			Teva
	Mycophenolate Mofetil			S	Oral			Teva
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown	300 Milligram Daily;		Not Reported
	Azathioprine			C	Oral	50 Milligram Daily;		Not Reported
	Azathioprine			C	Oral	150 Milligram Daily;		Not Reported
	Azathioprine			C	Unknown			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Ketoprofen			C	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Prolia Pre-Filled Preservative-Free			C	Subcutaneous			Not Reported

	Rituximab	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17811925	EXPEDITED (15-DAY)		HO	CA-ADVANZ PHARMA-202005005294			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Hydroxychloroquine			S	Unknown	Unknown		Concordia
	Arava			S	Unknown	Unknown		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Cortisone			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17811929	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600700		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gastric Disorder; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Off Label Use; Rash; Syncope; Urticaria	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prevacid			C	Unknown			Not Reported

	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17811956	EXPEDITED (15-DAY)		DE, HO	ES-FRESENIUS KABI-FK202004819		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Hypofibrinogenaemia; Upper Gastrointestinal Haemorrhage	Linezolid (Manufacturer Unknown)			S	Intravenous (not otherwise specified)	600 Mg Every 12 Hours		Fresenius Medical Care
	Meropenem (Manufacturer Unknown)			S	Intravenous (not otherwise specified)	1 G Every 8 Hours		Not Reported
	Piperacillin/Tazobactam 4g / 0.5g (Manufacturer Unknown)			S	Intravenous (not otherwise specified)	1 Df Every 8 Hours		Not Reported
	Tocilizumab			S				Not Reported
	Tocilizumab			S				Not Reported
	Metamizole			S	Intravenous (not otherwise specified)	2 G Every 8 Hours		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17811963	EXPEDITED (15-DAY)		DE, OT	MX-ADVANZ PHARMA-202005005293			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Off Label Use; Staphylococcal Infection	Hydroxychloroquine			S		200 Mg Every 12 Hours, Bid		Concordia
	Hydroxychloroquine			S				Concordia
	Clarithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812010	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601567		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity;	Rituximab			S	Intravenous (not			Not Reported

Drug Ineffective; Drug Intolerance; Seronegative Arthritis				otherwise specified)	
	Cosentyx		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Erythromycin		C	Unknown	Not Reported
	Methotrexate		C	Oral	Not Reported
	Morphine		C	Topical	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812011	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600095			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disease Recurrence; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Off Label Use; Pain; Sleep Disorder Due To General Medical Condition, Insomnia Type	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	8.0 Months		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	5.0 Months		Not Reported
	Gold			S	Unknown	7.0 Months		Not Reported
	Humira			S	Subcutaneous	7.0 Months		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	3.0 Years		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Sulfasalazine	S	Oral	5.0 Months	Not Reported
	Sulfasalazine	S	Oral	5.0 Months	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812069	EXPEDITED (15-DAY)		HO, LT, OT	FR-MYLANLABS-2020M1049048		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Cough; Covid-19; Headache; Intentional Product Misuse; Interstitial Lung Disease; Lung Opacity; Myalgia; Off Label Use; Pyrexia; Respiratory Failure	Prednisone			S		15 Mg Daily		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Four Infusions (375 Mg/M2) Were Weekly		Mylan
	Rituximab			S		Maintenance Therapy; 500 Mg		Mylan
	Hydroxychloroquine Sulfate			S		200 Mg/8 Hour For 10 Days From Day #19		Mylan
	Nebivolol			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812115	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598046			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812231	EXPEDITED (15-DAY)		DS, OT	MX-ADVANZ PHARMA-202005005296			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Depression; Hypoxia; Intentional Product Misuse; Pleural Effusion; Pyrexia; Visual Impairment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	2 Dosage Form, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	1 Dosage Form, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812256	EXPEDITED (15-DAY)		DE, OT	ES-PFIZER INC-2020200777		62 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Hypocoagulable State; Hypofibrinogenaemia; Off Label Use; Product Use In Unapproved Indication; Respiratory Failure; Thrombocytopenia	Azithromycin			S	Oral	500 Mg, Daily		Pfizer
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, Daily		Not Reported
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Mg, Daily		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Daily		Not Reported
	Enoxaparine			S	Subcutaneous	80 Mg, Unknown		Not Reported
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812349	EXPEDITED (15-DAY)		LT	FR-PFIZER INC-2020199194		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Ventricular Extrasystoles; Ventricular Tachycardia	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	600 Mg, 1x/Day		Not Reported
	Tazocilline			C		Unk		Not Reported
	Vialebex			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Levothyroxine Sodium			C		Unk		Not Reported
	Heparin Sodium			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Kardegic			C		75 Mg		Not Reported
	Hypnovel [Midazolam Hydrochloride]			C		Unk		Not Reported
	Rapifen [Alfentanil Hydrochloride]			C		Unk		Not Reported
	Sufenta			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812441	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020198949		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Hepatocellular Injury; Off Label Use; Product Use In Unapproved Indication	Methylprednisolone Sodium Succinate			S	Intravenous (not otherwise specified)	1 Mg/Kg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Roactemra			S		Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			C	Subcutaneous	2 Df, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812551	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2020198926		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Off Label Use; Product Use In Unapproved Indication; Ventricular Fibrillation	Azithromycine			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil			S	Oral	600 Mg, 1x/Day		Not Reported
	Irbesartan Eg			S	Oral	Unk		Not Reported
	Carvedilol Arrow			S	Oral	Unk		Not Reported
	Lasilix			S	Oral	Unk		Not Reported
	Risordan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812607	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1049321		86 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased; Off Label Use	Lopinavir/Ritonavir			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Mylan
	Dabigatran			S	Oral	110 Mg/Day X 2		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812616	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1049343		73 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased; Off Label Use	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported
	Apixaban			S	Oral	5 Mg/Day X 2		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812622	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1049342		69 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased; Off Label Use	Lopinavir/Ritonavir			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Mylan
	Apixaban			S	Oral	Unk(5 Mg/Day X 2)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812625	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1049357		62 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Off Label Use	Lopinavir/Ritonavir			S	Oral	1000 Milligram, Total		Not Reported
	Plaquenil /00072602/			S	Oral	400 Milligram, Total		Mylan
	Roactemra			S	Intravenous (not otherwise specified)	704 Milligram, Total		Mylan
	Inhixa			C		Unk		Mylan
	Piperacillina/Tazobactam			C		13.5 Gram		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812626	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1049326		89 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased; Off Label Use	Lopinavir/Ritonavir			S		Unk		Not Reported
	Apixaban			S	Oral	2.5 Mg/Day X 2		Mylan
	Hydroxychloroquine			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812696	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131577		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Sanofi
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Sanofi
	Methotrexate			S	Unknown	20 Mg		Not Reported
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Methotrexate			S	Unknown	200 Mg, Qw		Not Reported
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Enbrel			S	Unknown	25 Mg, Biw		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Q6w		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812701	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131492			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onycholysis; Tooth Loss	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Varicella Zoster Vaccine Live	S	Intravenous (not otherwise specified)		Not Reported
	Desoximetasone	C	Oral		Not Reported
	Diclofenac	C	Oral	100 Mg	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812706	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA131108			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Mefenamic Acid			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Unk Unk, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tylenol			C				Not Reported
	Prednisone			C		Unk Unk, Qd		Not Reported
	Prednisone			C	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812765	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1049416		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	3 Dosage Form, Qd		Mylan
	Lansoprazole			C	Oral	15 Milligram, Qd		Mylan
	Tamiflu			C	Oral	2 Dosage Form, Qd		Mylan
	Augmentin /00756801/			C	Intravenous (not otherwise specified)	3 Gram, Qd		Mylan
	Lovenox			C	Subcutaneous	1 Dosage Form, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812844	EXPEDITED (15-DAY)		OT	ES-ALVOGEN-2020-ALVOGEN-108420		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tinnitus	Fentanyl			S				Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200mg/12h		Not Reported
	Kaletra			S	Oral	5 Ml/12h		Not Reported
	Midazolam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812879	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1049499		64 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Tercian /00759301/			S	Oral	25 Milligram, Qd		Mylan

Prolonged	Plaquenil /00072603/	S	Oral	200 Milligram, Qd		Mylan
	Plaquenil /00072603/	S	Oral	200 Milligram, Bid		Mylan
	Paroxetine	C	Oral	30 Milligram, Qd		Mylan
	Depakine /00228501/	C	Oral	1000 Milligram, Qd		Mylan
	Aerius /01398501/	C	Oral	5 Milligram, Qd		Mylan
	Xanax	C	Oral	0.75 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812925	EXPEDITED (15-DAY)		HO	CA-ROCHE-2599304		86 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Off Label Use; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812965	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200515201		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use	Remicade			S	Intravenous (not otherwise specified)			Janssen

Actemra	S	Intravenous (not otherwise specified)	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813015	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601697		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Drug Ineffective; Drug Intolerance; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Migraine; Mobility Decreased; Nausea; Off Label Use; Pain In Extremity; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Therapeutic Product Effect Decreased; Vomiting; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

				otherwise specified)	
	Pantoprazole		C	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813024	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200514324			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapy Non-Responder; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813034	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200514312		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Pulmonary Fibrosis; Rheumatoid	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Gold			S	Intramuscular			Not Reported

Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Leflunomide		S	Oral	Not Reported
	Methotrexate		S	Oral	Not Reported
	Sulfasalazine		S	Rectal	Not Reported
	Xeljanz		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813038	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600125		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Arava	S	Oral	Not Reported
Celebrex	C		Not Reported
Diclofenac	C		Not Reported
Lyrica	C		Not Reported
Methotrexate	C		Not Reported
Sulfasalazine	C		Not Reported
Valsartan	C		Not Reported
Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813064	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598767		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Liver Injury; Loss Of Personal Independence In Daily Activities; Neck Pain; Nodule; Pain; Pain In Extremity; Swelling	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813177	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601625		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Drug Ineffective; Hypersensitivity; Joint Swelling; Maternal Exposure During	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Golimumab	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S		Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfathalidine	S	Unknown	Not Reported

Desoximetasone	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Diclofenac	C	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813252	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2020198921		71 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Feeling Hot; Flushing; Off Label Use; Product Use In Unapproved Indication; Product Use Issue; Senile Pruritus; Skin Exfoliation; Skin Reaction	Zitromax			S	Oral	500 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, 1x/Day		Not Reported
	Rezolsta			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813289	EXPEDITED (15-DAY)		DS	CA-ROCHE-2600406		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Asthenia; C-Reactive Protein Increased; Cataract; Constipation; Drug Ineffective; Fatigue; Hepatic Cirrhosis; Herpes Zoster; Joint Injury; Loss Of Personal Independence In Daily Activities; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813295	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1049663		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Tinnitus	Fentanyl			S		Unk		Not Reported
	Azitromicina			S	Intravenous (not otherwise specified)	Unk		Mylan
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	Unk		Mylan
	Kaletra			S	Oral	5 Milliliter, Bid (5 Ml/12h)		Mylan
	Midazolam			S		Unk		Mylan
	Hidroxicloroquina /00072601/			S	Oral	200 Milligram, Bid (200mg/12h)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813311	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1235960		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Privigen 100mg/Ml Solucion Para Perfusion , 1 Vial De 400 Ml			S	Intravenous (not otherwise specified)			Not Reported
	Roactemra			S	Intravenous (not otherwise specified)	600 Milligram Daily;		Not Reported

Azitromicina (7019a)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813329	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1236090		26 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Dexametasona (722a)			S	Intravenous (not otherwise specified)	20 Milligram Daily;		Not Reported
	Enoxaparina (2482a)			S	Subcutaneous	40 Milligram Daily;		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab (8289a)			S				Not Reported
	Dexketoprofeno (7312a)			S	Intravenous (not otherwise specified)	75 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813343	EXPEDITED (15-DAY)		OT	NVSC2020US140080			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Bradycardia; Cardiomyopathy; Electrocardiogram Qt Prolonged; Hypothermia; Product Use In Unapproved Indication; Torsade De Pointes; Ventricular Arrhythmia	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Azithromycin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813420	NON-EXPEDITED			US-PFIZER INC-2020197950			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Fatigue; Off Label Use; Product Use In Unapproved Indication	Zinecard		S	Unk	Pfizer
	Azithromycin		S	Unk	Pfizer
	Hydroxychloroquine Sulfate		S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813445	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1049616		48 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tachycardia	Amlodipine Besilate/Valsartan			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813449	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238634		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Risedronate			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813842	EXPEDITED (15-DAY)		OT	ES-JNJFOC-20200518237		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use; Product Use In Unapproved Indication; Tinnitus	Durogesic Matrix		S	Unknown		Janssen
	Ceftriaxone		S	Intravenous (not otherwise specified)		Not Reported
	Kaletra		S	Oral	5 Ml/12h	Not Reported
	Midazolam		S	Unknown		Not Reported
	Hydroxychloroquine		S	Oral	200mg/12h	Not Reported
	Azitromicina		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17814201	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602587			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Rituximab			S	Intravenous drip			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17814262	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238635		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Nausea; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Risedronate Sodium			S	Unknown			Teva
	Risedronate Sodium			S	Oral			Teva
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported

	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquinesulfate	S	Unknown			Not Reported
	Hydroxychloroquinesulfate	S	Oral	300 Milligram Daily;		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17814270	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238637		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Off Label Use; Pulmonary Fibrosis; Rheumatoid Factor Positive; Synovitis	Risedronate Sodium			S	Unknown			Teva
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Remicade		S	Intravenous (not otherwise specified)			Not Reported
	Rituximab		S	Intravenous (not otherwise specified)			Not Reported
	Simponi		S	Subcutaneous			Not Reported
	Xeljanz		S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	10653444	EXPEDITED (15-DAY)		DS	FR-009507513-1412FRA006146		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Peripheral Sensorimotor Neuropathy	Fosamax			S	Oral	Unk		Merck
	Lasilix			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Lexomil			S	Oral	Unk		Not Reported
	Cacit Vitamine D3			S	Oral	Unk		Not Reported
	Rivotril			S	Oral	Unk		Not Reported
	Avodart			S	Oral	Unk		Not Reported
	Cymbalta			S	Oral	Unk		Not Reported
	Inexium (Esomeprazole Magnesium)			S	Oral	Unk		Not Reported
	Salazopyrine			S	Oral	Unk		Not Reported
	Tahor			S	Oral	Unk		Not Reported
	Forlax			S	Oral	Unk		Not Reported
	Skenan			S	Oral	Unk		Not Reported
	Cortancyl			S	Oral	Unk		Not Reported
	Metoject			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	11385922	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-ROCHE-1619365		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Photosensitivity Reaction; Product Use In Unapproved Indication; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stomatitis; Thrombosis; Urticaria	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Arava	S			Not Reported
Sodium Aurothiomalate	S	Intramuscular		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S			Not Reported
Cannabis Sativa	S	Unknown		Not Reported
Gold	S	Unknown		Not Reported
Gold	S			Not Reported
Ilaris	S	Subcutaneous		Not Reported
Ilaris	S	Unknown		Not Reported
Minocycline	S	Unknown		Not Reported
Minocycline Hydrochloride	S	Unknown		Not Reported
Oxycodone	S	Unknown		Not Reported
Oxyquinoline Sulfate	S	Unknown		Not Reported
Oxyquinoline Sulfate	S			Not Reported
Lyrica	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	11565068	EXPEDITED (15-DAY)		DS, LT, OT	CA-009507513-1509CAN012569			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Abdominal Pain Upper; Adverse Drug Reaction; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Discomfort; Dizziness; Drug Ineffective; Drug Intolerance; Duodenal	Fosamax			S	Oral	Unk		Merck
	Fosamax			S		Route: Intra Corpus Cavernosum		Merck
	Fosamax			S	Unknown	Unk		Merck
	Cortisone Acetate			S	Unknown	25 Mg, Unk		Not Reported
	Methotrexate			S	Intra-arterial	25 Mg, 1 Every 1 Week(S)		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk, Qd		Not Reported
	Methotrexate			S	Unknown	20.0 Milligram, 1 Every 1 Days; Solution		Not Reported
	Methotrexate			S	Oral	25.0 Milligram		Not Reported

Ulcer Perforation; Exposure During Pregnancy; Fatigue; Fibromyalgia; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Nausea; Oedema; Off Label Use; Pain; Pemphigus; Pericarditis; Prescribed Overdose; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting; Wheezing; Wound	Methotrexate	S		25.0 Milligram	Not Reported
	Methotrexate	S	Oral	20.0 Milligram, 1 Every 1 Days	Not Reported
	Methotrexate	S	Intra-arterial	25 Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
	Simponi	S	Subcutaneous	Unk; Solution Subcutaneous	Not Reported
	Apo Prednisone	S	Unknown	5 Milligram	Not Reported
	Apo Prednisone	S	Unknown	Unk	Not Reported
	Apo Prednisone	S		1 Milligram	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qw	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	20 Milligram, Unknown	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg/0.8 Ml, Solution For Injection In Prefilled Syringe	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Plaquenil	S	Oral	400 Mg, 1 Every 1 Day(S)	Not Reported
	Plaquenil	S	Oral	400 Mg, 1 Every 1 Day(S)	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported

Sulfasalazine	S	Oral	1 Gram, 2 Every 1 Day(S)	Not Reported
Sulfasalazine	S	Unknown	500 Milligram, Unknown	Not Reported
Apo Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
Apo Folic Acid	S	Unknown	1, Unk	Not Reported
Apo Folic Acid	S	Unknown	15 Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S			Not Reported
Zyrtec	S	Unknown	25 Milligram	Not Reported
Cortisone	S	Unknown	Unk	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	400 Mg, Q24h	Not Reported
Desoximetasone	S	Oral	Unk; Dosage Form: Not Specified	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Cutaneous	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Milligram, Qd	Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Milligram, Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	25 Milligram	Not Reported
Diclofenac Sodium	S	Unknown	Unk; Dosage Form Not Specified	Not Reported
Cetirizine Hydrochloride (+) Pseudoephedrine Hydrochloride	S	Unknown	25.0 Milligram	Not Reported
Cetirizine Hydrochloride (+) Pseudoephedrine Hydrochloride	S	Unknown	10.0 Milligram	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Topicort (Hydrocortisone Acetate)	S	Subcutaneous	Unk	Not Reported
Topicort (Hydrocortisone Acetate)	S	Unknown	Unk, Other	Not Reported

Topicort (Hydrocortisone Acetate)	S	Cutaneous	Unk; Dosage Form Not Specified	Not Reported
Folic Acid	S	Oral	500 Milligram Per Litre, Unknown	Not Reported
Folic Acid	S	Unknown	1.0 Milligram, Unknown	Not Reported
Folic Acid	S	Unknown	5.0 Milligram	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk, Unknown	Not Reported
Hydroxychloroquine Sulfate	S		400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	4000.0 Milligram, 1 Every 1 Days	Not Reported
Prednisone	S	Unknown	Unk; Dosage Form: Not Specified	Not Reported
Naproxen Sodium	S	Unknown	500 Milligram, 2 Every 1 Days	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Acetaminophen	S	Unknown	Unk, Unknown	Not Reported
Tofacitinib Citrate	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride (+) Phenylephrine Hydrochloride	S	Unknown	10.0 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Topicort (Desoximetasone)	S	Oral	Unk	Not Reported
Topicort (Desoximetasone)	S	Other	Unk	Not Reported
Topicort (Desoximetasone)	S	Subcutaneous	Unk	Not Reported
Certolizumab Pegol	S	Unknown	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported

	Salazopyrin	C	Unknown	Unk	Not Reported
	Atasol (Acetaminophen)	C	Unknown	Unk	Not Reported
	Atasol (Acetaminophen)	C			Not Reported
	Tofacitinib Citrate	C	Unknown	Unk	Not Reported
	Ibuprofen	C	Unknown	Unk	Not Reported
	Prinivil	C	Unknown	Unk	Merck
	Cholecalciferol	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Zyrtec	C	Unknown	Unk	Not Reported
	Tofacitinib	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	12422597	EXPEDITED (15-DAY)		OT	CA-ROCHE-1766629		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Piroxicam	S	Unknown	Not Reported
	Prednisone	S	Urethral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Cimzia	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Morphine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	12842578	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1958		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Haematocrit Decreased; Haemoglobin Decreased; Inappropriate Schedule Of Product Administration; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Pantoloc			S	Unknown			Not Reported

Pantoloc	S	Unknown		Not Reported
Apo Folic Acid	S	Unknown	Twice In A Week	Not Reported
Apo Folic Acid	S	Unknown	Twice A Week	Not Reported
Naprosyn	S	Oral		Not Reported
Naprosyn	S	Oral		Not Reported
Naprosyn	S	Oral		Not Reported
Naprosyn	S	Oral		Not Reported
Palafer Cf	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Adalimumab	S	Subcutaneous		Not Reported
Abatacept	S	Unknown		Not Reported
Ascorbic Acid	S	Unknown		Not Reported
Ferrous Fumarate	S	Unknown		Not Reported

Folic Acid	S	Unknown		Not Reported
Folic Acid	S	Unknown	2/Week	Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Pantoprazole Sodium Anhydrous	S	Unknown		Not Reported
Pantoprazole Sodium Anhydrous	S	Unknown		Not Reported
Ferrous Fumarate-Folic Acid	S	Unknown		Not Reported
Pantoprazole Sodium Sesquihydrate	S	Unknown		Not Reported
Naproxen	S	Oral		Not Reported
Naproxen	S	Oral		Not Reported
Naproxen	S	Oral		Not Reported
Leflunomide	S	Oral		Not Reported
Atenolol	S	Unknown		Not Reported
Remicade	S	Unknown		Not Reported
Naproxen Sodium	S	Unknown		Not Reported
Naproxen Sodium	S	Unknown		Not Reported
Naproxen Sodium	S	Oral		Not Reported
Naproxen Sodium	S	Oral		Not Reported
Naproxen Sodium	S	Oral		Not Reported
Etanercept	S	Unknown		Not Reported
Palafer	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Pantoprazole Sodium	S	Unknown		Not Reported
Pantoprazole Sodium	S	Unknown		Not Reported
Pantoprazole Teva	S	Unknown		Not Reported

	Pantoprazole Teva	S	Unknown	Not Reported
	Ferrous Fumarate;Folic Acid	S	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Celecoxib	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	12922824	EXPEDITED (15-DAY)		OT	CA-ROCHE-1849821		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Anaphylactic Reaction; Arthralgia; Blood Glucose Increased; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Off Label Use; Pain; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatic Disorder; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Swelling; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Increased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Intra-arterial			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Hydroxychloroquine	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Pregabalin	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Urethral	Not Reported
Mycophenolate Mofetil Hydrochloride	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Piroxicam	C	Unknown	Not Reported
Levothyroxine	C	Unknown	Not Reported
Morphine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	13015664	EXPEDITED (15-DAY)		OT	CA-ROCHE-1865625		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

Enbrel	S	Subcutaneous	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Imuran [Azathioprine]	S	Unknown	Not Reported
Cimzia	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	13237837	EXPEDITED (15-DAY)		OT	CA-ROCHE-1893817		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Synovitis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Sulfasalazine	S	Unknown	Not Reported
	Zostavax	S	Subcutaneous	Not Reported
	Varicella Zoster Vaccine Live	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Desoximetasone	C	Oral	Not Reported
	Desoximetasone	C	Subcutaneous	Not Reported
	Desoximetasone	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Subcutaneous	Not Reported
	Voltaren [Diclofenac]	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	13538108	EXPEDITED (15-DAY)		OT	CA-ROCHE-1933679			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Incorrect Route Of Product Administration; Insomnia; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

Orencia	S	Endocervical		Not Reported
Vioxx	S	Unknown		Not Reported
Naprosyn [Naproxen]	S	Oral		Not Reported
Leflunomide	C	Unknown		Not Reported
Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	13614636	EXPEDITED (15-DAY)		DS	CA-ROCHE-1942553			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Arava			S	Oral			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Erythematosus; Treatment Failure; Wound	Simponi	S	Subcutaneous	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride;Ibuprofen;Phenylephrine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride;Ibuprofen;Phenylephrine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Golimumab	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Kevzara	S	Subcutaneous	Not Reported
	Leflunomide	S	Oral	Not Reported
	Paracetamol	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Stelara	S	Unknown	Not Reported
	Topicorte	S	Subcutaneous	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C		Not Reported
	Salazopyrina	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	13628309	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20170602995		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Disability; Disease Recurrence; Drug Ineffective; Dyspnoea; Impaired Work Ability; Infection; Insomnia; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Off Label Use; Pain; Peripheral Swelling; Physical Disability; Rash; Rheumatoid Arthritis; Skin Mass; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapeutic Product Effect Decreased; Therapy Non-Responder	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Avara	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone Acetate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Risedronate Sodium	C	Unknown	Not Reported

	Sulfasalazine	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	14267213	EXPEDITED (15-DAY)		OT	CA-ROCHE-2032902		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Off Label Use; Pain; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatic Disorder; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Cimzia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Gold			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

	Mycophenolate Mofetil Hydrochloride	S	Unknown		Not Reported
	Mycophenolate Mofetil Hydrochloride	S	Subcutaneous		Not Reported
	Piroxicam	C			Not Reported
	Prednisone	C	Unknown		Not Reported
	Morphine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	14535557	EXPEDITED (15-DAY)		CA, OT	CA-BIOVITRUM-2018CA0126			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Incorrect Route Of Product Administration; Insomnia; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis	Anakinra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown	2 Every 1 Weeks 1 Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naprosyn			S	Oral			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Naprosyn			S	Oral			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Orencia			S	Endocervical			Not Reported
	Rituximab			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Naproxen			S				Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

	Leflunomide			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	14539306	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0138		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Joint Swelling; No Adverse Event; Renal Impairment; Therapeutic Product Effect Incomplete	Kineret			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo Hydroxychloroquine			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S				Not Reported
	Apo-Azathioprine			S				Not Reported
	Gold			S	Intramuscular			Not Reported
	Hydroxychloroquine			S				Not Reported
	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	14788235	EXPEDITED (15-DAY)		OT	CA-ROCHE-2108819		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition	Rituxan			S	Intravenous (not			Not Reported

Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Ill-Defined Disorder; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive			otherwise specified)	
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Celecoxib	S	Oral	Not Reported
	Celecoxib	S	Oral	Not Reported
	Celecoxib	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Toradol	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Tramadol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	15049785	EXPEDITED (15-DAY)		HO	CA-ROCHE-2141880		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired	Actemra			S	Unknown			Not Reported
	Aleve			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Methotrexate	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone Acetate	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Naproxen	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Novo-Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Naproxen	S	Unknown	Not Reported
	Folic Acid	C	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	15157332	EXPEDITED (15-DAY)		OT	CA-ROCHE-2155675			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Arthralgia; Bronchitis; C-Reactive Protein Increased; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspepsia; Fear; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Off Label Use; Pneumonia; Pneumonia; Treatment Failure	Rituxan			S	Intravenous drip	Solution Intravenous		Not Reported
	Arava			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

	Desoximetasone	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	15369246	EXPEDITED (15-DAY)		OT	CA-ROCHE-2181844		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Joint Swelling; Pneumonia; Pneumonia; Treatment Failure	Rituximab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringemide		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lidocaine Hydrochloride			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Cephalexin [Cefalexin]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	15372794	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2182468			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Simponi	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Arava	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	15470572	EXPEDITED (15-DAY)		OT	PHHY2016CA163833		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthritis; Blood Glucose Abnormal; Blood Pressure Increased;	Sandostatin			S	Subcutaneous	50 Ug, Once/Single (Test Dose)		Novartis
	Sandostatin Lar			S	Intramuscular	30 Mg, Qmo		Novartis

Cataract; Cholelithiasis; Dizziness; Ear Discomfort; Erythema; Facial Neuralgia; Fatigue; Groin Pain; Headache; Hypotension; Inappropriate Schedule Of Product Administration; Joint Stiffness; Labyrinthitis; Muscle Spasms; Nausea; Rheumatoid Arthritis; Visual Impairment; Vomiting	Sandostatin Lar	S	Intramuscular	30 Mg, Qmo	Novartis
	Atorvastatin	S	Unknown	10 Mg, Qd	Not Reported
	Bisoprolol	S	Unknown	2.5 Mg, Bid	Not Reported
	Plaquenil	S	Unknown	200 Mg, 2 Tablets Once A Day	Not Reported
	Forxiga	C	Unknown	5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	15476259	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP022037			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; Colitis; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency	Amlodipine			S	Oral	5 Mg, Qd		Apotex
	Asacol			S	Oral	800 Mg, Tid		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Amlodipine Besilate			C	Unknown	Unk		Not Reported
	Atacand Plus			C	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			C	Unknown	Unk		Not Reported
	Depo-Medrol			C	Intra-articular	Unk		Not Reported
	Ferrous Gluconate			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported

	Omega Allergenic Extracts		C	Unknown	Unk	Not Reported
	Tylenol /00020001/		C	Unknown	Unk	Not Reported
	Vitamin D3		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	15957816	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190213604			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Ankylosing Spondylitis; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Inability; Hypermobility Syndrome; Loss Of Personal Independence In Daily Activities; Migraine; Nausea; Rheumatoid Arthritis; Somnolence; Unevaluable Event; Vertigo; Visual Impairment; Vomiting	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Arava			S	Oral			Not Reported
	Hydromorphone Hydrochloride			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported

	Hydromorphone	S	Unknown	Not Reported
	Hydromorphone	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Fentanyl	S		Not Reported
	Fentanyl	S		Not Reported
	Etanercept	S		Not Reported
	Lolo	C	Oral	Not Reported
	Diclofenac	C		Not Reported
	Indomethacin /00003801/	C	Unknown	Not Reported
	Acetaminophen W/Codeine Phosphate	C	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	16739745	EXPEDITED (15-DAY)		OT	DE-ACCORD-152811			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Ramipril			S	Oral	1 Df, 2x/Day (1 - 0 - 1) 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Accord
	Pregabalin			S	Unknown	1 Df, Tid (1 - 1 - 1)		Not Reported
	Sildenafil/Sildenafil Citrate			S	Unknown	60 Milligram, Daily Dose		Not Reported
	Ambrisentan			S	Unknown	1 Dosage Form, Qd		Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qw		Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1 - 0 - 1) 1 Number Of Units In The Interval: 12 Definition Of The Interval		Not Reported
	Eliquis			S	Unknown	1 Df, Bid (1 - 0 - 1) 2.5 Mg Twice Daily		Not Reported
	Omeprazole			S	Oral	1 Df, 2x/Day (1 - 0 - 1) 1 Number Of Units In The		Not Reported

			Interval: 12 Definition Of The Interval: Hour	
Spasmolyt	S	Unknown	1 Df, Qd 1 Number Of Units In The Interval: 1 Definition Of The Interval: Day	Not Reported
Volibris	S	Oral	30 Milligram, Qd	Not Reported
Lyrica	S	Unknown	100 Milligram, Tid	Not Reported
Apixaban	S		2.5 Milligram, Bid	Not Reported
Trospium Chloride	S		30 Mg, Qd Number Of Separate Dosages: 1 Number Of Units In The Interval: 1 Definition Of The Interv	Not Reported
Volibris	S	Oral	1 Dosage Form, Qd	Not Reported
Roactemra	S	Subcutaneous	162 Mg, Qw	Not Reported
Ambrisentan	S	Unknown	30 Mg, Qd	Not Reported
Omeprazole	S	Oral	1 Df, 2x/Day (1 - 0 - 1) 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour	Not Reported
Apixaban	S		2.5 Milligram, Bid	Not Reported
Quensyl	S	Unknown	1 Df, Bid (1 - 0 - 1) 1 Number Of Units In The Interval: 12 Definition Of The Interval	Not Reported
Ramipril	S	Oral	1 Df, 2x/Day (1 - 0 - 1) 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour	Accord
Quensyl	S	Unknown	1 Df, Bid (1 - 0 - 1) 1 Number Of Units In The Interval: 12 Definition Of The Interval	Not Reported
Spasmolyt	S	Unknown	1 Df, Qd 1 Number Of Units In The Interval: 1	Not Reported

Definition Of The Interval:
Day

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	16884438	EXPEDITED (15-DAY)		OT	CA-ROCHE-2418381			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Infection; Joint Swelling; Liver Function Test Increased; Off Label Use; Pain; Paralysis; Skin Infection; Treatment Failure; Urinary Tract Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz Xr			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Diphenhydramine			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported
	Hydroxychloroquine			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17288297	EXPEDITED (15-DAY)		OT	CA-ROCHE-2522989		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell	Rituximab			S	Unknown			Not Reported

Carcinoma; Diarrhoea; Renal Mass; Vomiting	Azathioprine	S	Unknown	Not Reported
	Cyclosporin A	S	Unknown	Not Reported
	Depo-Provera	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Naprosyn [Naproxen]	S	Unknown	Not Reported
	Amitriptyline	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17620330	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002212			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Infection	Hydroxychloroquine			S		400 Mg, Qd		Concordia
	Hydroxychloroquine			S				Concordia
	Aminosalicylic Acid			S		81 Mg, Qd		Not Reported
	Aminosalicylic Acid			S				Not Reported
	Mycophenolate Mofetil			S		1 G, Qd		Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Quinacrine			C		100 Mg, Qd		Not Reported
	Quinacrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17682088	EXPEDITED (15-DAY)		OT	DE-ACCORD-179153		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Granuloma; Infective Tenosynovitis; Mycobacterium Marinum Infection	Methotrexate			S	Subcutaneous			Accord
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral	Intermittent Usage		Not Reported
	Sulfasalazine			S	Oral	Strength 500 Mg		Not Reported
	Prednisolone			S	Oral	Intermittent Usage Of Low-Dose Prednisolone. Also Received 30 Mg, 7.5 Mg, 5 Mg, 40 Mg, 20 Mg, 10 Mg		Not Reported
	Prednisone			S		Increased To		Not Reported
	Metoprolol			C				Not Reported
	Amlodipine			C				Not Reported
	Prednisone			S				Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral	Two Weeks Before Presentation		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17724510	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA1948		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Endodontic Procedure; Flushing; Heart Rate Decreased; Herpes Zoster; Ill-Defined Disorder; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error;	Kineret			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Discolouration; Skin Disorder; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Methotrexate	S	Unknown		Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Naproxen	S	Unknown	1000 Milligram	Not Reported
	Rituximab	S		1000 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Plaquenil	S			Not Reported
	Acetaminophen	C	Oral		Not Reported
	Diphenhydramine Hydrochloride	C	Oral		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Lasix	C	Unknown		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)		Not Reported
	Naprosyn	C	Unknown		Not Reported
	Oxycontin	C	Unknown		Not Reported
	Oxyneo	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17727246	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010388		46 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Condition Aggravated; Drug Ineffective; Gait Disturbance; Herpes Zoster; Musculoskeletal Pain; Musculoskeletal Stiffness; Rheumatoid Arthritis	Leflunomide	S	Oral	20 Mg, Qd		Apotex
	Methotrexate	S	Unknown	Unk		Not Reported
	Enbrel	S	Unknown	50 Mg, Q.Wk.		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072603/	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Celebrex	C	Unknown	Unk		Not Reported
	Tramacet	C	Unknown	Unk		Not Reported
	Tramadol	C	Unknown	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17727437	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP010336		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Back Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Joint Lock; Joint Swelling; Pain; Polyarthritis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd (Therapy Duration: 518 Unit Unspecified)		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	25 Mg, Q.Wk.		Not Reported
	Xeljanz			C	Oral	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17744196	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436856			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity;	Remicade			S	Intravenous (not			Janssen

Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17746486	EXPEDITED (15-DAY)		OT	CA-SA-2020SA114212			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Desoximetasone			S	Oral			Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S	Oral			Sanofi
	Cetirizine Hydrochloride			S				Not Reported
	Folic Acid			S				Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Prednisone			S				Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S		400 Mg, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous	Not Reported
	Tofacitinib Citrate	S		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17761776	EXPEDITED (15-DAY)		DE, HO, OT	FR-ADVANZ PHARMA-202003004184			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Hospitalisation; Off Label Use; Unevaluable Event	Hydroxychloroquine			S	Unknown	Unknown		Concordia
	Hydroxychloroquine			S				Concordia
	Azithromycin			C		Unknown		Not Reported
	Biguanides			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17763474	EXPEDITED (15-DAY)		HO	US-ROCHE-2594510		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Deep Vein Thrombosis; Intentional Product Use Issue; Off Label Use	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Remdesivir			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enoxaparin			C				Not Reported
	Oxygen			C				Not Reported
	Loperamide			C				Not Reported
	Lovenox [Enoxaparin Sodium]			C				Not Reported
	Zosyn			C				Not Reported
	Tylenol			C				Not Reported
	Vancomycin			C				Not Reported
	Zithromax			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Potassium Chloride			C				Not Reported
	Cholecalciferol			C				Not Reported
	Melatonin			C				Not Reported

	Multivitamin And Mineral			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17767076	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594973		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Advil [Ibuprofen]			C				Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17768317	EXPEDITED (15-DAY)		HO	US-CELLTRION INC.-2020US022161			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Gastric Disorder; Impaired Work Ability; Infected Lymphocele; Inguinal Hernia; Pneumonitis; Poor Quality Sleep; Prostate Cancer; Psoriasis; Septic Shock; Urticaria	Infliximab (Unknown)			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Remicade			S				Not Reported
	Leflunomide			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Levofloxacin			S				Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Methylprednisolone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17769513	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596273			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17778024	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200505945			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Hydroxychloroquine			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Tofacitinib Citrate			C	Oral	Extendedrelease		Not Reported
	Infliximab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17778044	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200505943			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Leflunomide			S	Oral			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Arava	C	Unknown	Not Reported
Naproxen	C	Unknown	Not Reported
Viread	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17778065	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200505942			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Neck Pain; Off Label Use; Spinal Column Injury; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17778124	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200505936		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Carpal Tunnel Syndrome; Condition Aggravated; Fatigue;	Remicade			S	Intravenous (not otherwise specified)			Janssen

Headache; Inflammation; Insomnia; Joint Swelling; Migraine; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Pain; Pain In Extremity; Paraesthesia; Rheumatoid Arthritis; Rhinorrhoea; Treatment Failure	Arava	S	Oral		Not Reported
	Celebrex	S	Unknown	2 Dosage Forms	Not Reported
	Enbrel	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Oral		Not Reported
	Sulfasalazine	S	Rectal		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine /00072603/	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17778166	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200505927		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Allergic Oedema; Arthrodesis; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Infection; Joint Surgery; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty; Urticaria	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

		otherwise specified)	
Methotrexate	S	Subcutaneous	Not Reported
Naproxen	C	Unknown	Not Reported
Viread	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17780182	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200505924		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Anaphylactic Shock; Drug Ineffective; Drug Intolerance; Nasopharyngitis; Pain; Synovitis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17780358	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200505849		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Reaction; Anaphylactic Shock; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Nasopharyngitis; Pain; Synovitis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17782408	EXPEDITED (15-DAY)		HO, LT	ES-ACCORD-181852		26 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Psychosis; Off Label Use; Suicide Attempt	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Allopurinol			C	Oral	100 Mg Tablet		Not Reported
	Paracetamol			C	Oral			Not Reported
	Famotidine			C	Oral	20 Mg Tablet		Not Reported
	Doxazosin			C	Oral			Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	2,000 Mg Injection Iv		Not Reported
	Cefixime/Cefixime Trihydrate			C	Oral			Not Reported
	Magnesium Chloride Anhydrous			C	Oral	53 Mg Coated Tablets		Not Reported
	Prednisone			C	Oral			Not Reported
	Carvedilol/Carvedilol Hydrochlodride			C	Oral	25 Mg Tablet		Not Reported
	Zemplar			C	Oral	1 Microgram Soft Capsules		Not Reported
	Myfortic			C	Oral	360 Mg Gastro-Resistant Tablets		Not Reported
	Enoxaparin			C	Subcutaneous	20 Mg (2,000 Iu) Injection 0.2 Ml		Not Reported
	Fosrenol			C	Oral			Not Reported
	Metamizole Sodium			C	Oral	575 Mg Capsule		Not Reported
	Tacrolimus			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Tacrolimus			C	Oral			Not Reported
	Tacrolimus			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17791629	EXPEDITED (15-DAY)		DE	ES-ACCORD-181888		84 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Hydroxychloroquine			S	Oral	400 Mg Loading Dose Followed By 200 Mg / Day		Not Reported
	Azithromycin			C	Oral			Not Reported
	Hydroxychloroquine			S	Oral	Loading Dose Of 400 Mg Every 12 Hours Followed By 200 Mg Every 12 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17800794	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187427		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Methotrexate	S	Parenteral	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Actemra	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Tofacitinib	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17807175	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598861		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Nausea; Off Label Use; Off Label Use; Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency; Weight	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Amlodipine Besilate			S	Oral			Not Reported
	Amlodipine Besilate			S	Oral			Not Reported
	Asacol			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Decreased; Weight Increased	Plaquenil [Hydroxychloroquine Sulfate]	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Acetaminophen	C	Oral	Not Reported
	Atacand Plus	C	Unknown	Not Reported
	Bisoprolol Fumarate	C	Unknown	Not Reported
	Depo-Medrol	C		Not Reported
	Diamicron	C	Unknown	Not Reported
	Diphenhydramine	C	Oral	Not Reported
	Ebastine	C		Not Reported
	Ferrous Gluconate	C		Not Reported
	Folic Acid	C		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
	Rosuvastatin Calcium	C		Not Reported
	Tylenol	C		Not Reported
	Vitamin D3	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17809339	EXPEDITED (15-DAY)		OT	CA-ROCHE-2026232		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hypertension; Off Label Use; Therapeutic Product Effect Decreased	Rituximab			S	Unknown	Therapy Duration: 4 Years		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 155 Days		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Therapy Duration: 519 Nos		Not Reported

	Methotrexate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Hydromorphone Hydrochloride	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Valsartan	C		Not Reported
	Cortisone	C		Not Reported
	Desoximetasone	C		Not Reported
	Hydromorphone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17811582	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599879		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Oropharyngeal Pain; Pain; Pulmonary Embolism; Swelling; Upper-Airway Cough Syndrome	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Warfarin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17812560	EXPEDITED (15-DAY)		DE	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050635			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Tachyarrhythmia	Azithromycin			S	Oral			Zydus Pharm
	Hidroxicloroquina			S	Oral	200 Milligram		Not Reported

	[Hydroxychloroquine Sulfate]					
	Ceftriaxon	C	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Tocilizumab	C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17812589	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020198870		83 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hyponatraemia; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, 1x/Day		Not Reported
	Symbicort Turbohaler			S	Respiratory (inhalation)	2 Df, 3x/Day(2-2-2; 2df/8 Hours)		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Salbutamol			S	Respiratory (inhalation)	2 Df, 3x/Day(2-2-2 Inh)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814115	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598381			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Meloxicam	C			Not Reported
	Sulfasalazine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814211	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601674			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Off Label Use; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814348	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201711-006311			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass;	Hydroxychloroquine			S	Oral	200 Mg, Bid		Concordia

Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine	S	Oral	200 Mg, Bid	Concordia
	Arava	S	Oral	20 Mg, Qd	Not Reported
	Enbrel	S	Unknown	50 Mg, Weekly	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
	Methotrexate	S	Oral	175 Mg, Weekly	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814398	EXPEDITED (15-DAY)		HO, OT	BR-ADVANZ PHARMA-202005005520			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Azithromycine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814418	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598071			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatic Cirrhosis; Off Label Use; Synovitis; Treatment Failure; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814475	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597810			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Intentional Product Use Issue; Off Label Use; Pneumonia	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814493	EXPEDITED (15-DAY)		HO	CA-ROCHE-2597972			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814506	EXPEDITED (15-DAY)		HO	CA-ROCHE-2597907			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Synovitis; Vomiting	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Unknown	Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814516	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597952		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Fatigue; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Neoral	S	Oral	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814573	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599215		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported
	Diclofenac			C				Not Reported
	Pantoprazole Magnesium			C				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C	Unknown			Not Reported

Upper Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814592	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599622		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Asthenia; Bone Erosion; Contraindicated Product Administered; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gastric Disorder; Gingival Bleeding; Headache; Hereditary Angioedema; Infection; Liver Function Test Abnormal; Liver Function Test Increased; Nausea; Rash; Syncope; Urticaria	Actemra			S	Intravenous (not otherwise specified)	365.0		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	366.0		Not Reported
	Arava			S	Oral	366.0		Not Reported
	Enbrel			S	Subcutaneous	3.0 Months		Not Reported
	Humira			S	Subcutaneous	3.0 Months		Not Reported
	Humira			S	Subcutaneous	366.0		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	16.0 Years		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	638.0		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	8.0 Years		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	396.0		Not Reported
	Xeljanz			C	Oral			Not Reported
	Prednisone			C				Not Reported
	Prevacid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814607	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599715		73 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cardiac Failure Congestive; Diverticulitis; Drug Ineffective; Dyspnoea; Eye Disorder; Lung Disorder; Product Dispensing Error; Pulmonary Toxicity; Sensitivity To Weather Change; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown	Frequency: Cyclical		Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Therapy Duration: 6.0 Months		Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Acetaminophen;Oxycodone Hydrochloride			C				Not Reported
	Asa			C	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported
	D-Alpha Tocopherol			C	Unknown			Not Reported
	Endocet			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Indomethacin [Indometacin]			C				Not Reported
	Macrogol			C				Not Reported
	Metoprolol			C	Unknown			Not Reported
	Naproxen Sodium			C	Unknown			Not Reported
	Pennsaid			C	Topical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814629	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599754			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814651	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602457			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814669	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602466		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Off Label Use; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported

	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814676	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597811		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814706	EXPEDITED (15-DAY)		HO	CA-ROCHE-2600418			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Medication Error; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814711	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA131305		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Hydroxychloroquine			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Leflunomide			S		Unk		Sanofi
	Sulfasalazine			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Anakinra			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab	C		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C		Unk		Not Reported
	Ilaris	C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814822	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600568			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Off Label Use; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	Therapy Duration: 7.0 Months		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Gabapentin			C	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814831	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598090			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Burning Sensation; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			C	Oral			Not Reported
	Rabeprazole Sodium			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814839	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598481		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Arthropathy; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Musculoskeletal Disorder; Off Label Use; Skin Warm	Actemra		S	Unknown		Not Reported
	Arava		S	Oral		Not Reported
	Arava		S	Unknown		Not Reported
	Cimzia		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Orencia		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral		Not Reported
	Methotrexate		C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814864	EXPEDITED (15-DAY)		LT	ES-TEVA-2020-ES-1239014		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intrusive Thoughts; Suicide Attempt	Hidroxicloroquina (2143a)			S	Oral	200mg Every 12 Hours		Teva
	Levofloxacino (2791a)			C	Unknown			Not Reported
	Cortic - Corticoide			C	Intravenous bolus	Bolus Corticosteroids Iv		Not Reported
	Septrin			C	Unknown			Not Reported
	Kaletra			C	Oral			Not Reported
	Acetilcisteina (233a)			C	Unknown			Not Reported
	Ciclosporina (406a)			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814963	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601285		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Pain; Rheumatoid Arthritis;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported

Stomatitis; Swelling	Doxycycline	S	Unknown	Not Reported
	Doxycycline	S	Unknown	Not Reported
	Doxycycline Hyclate	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814968	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600417			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

	Leflunomide	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17814994	EXPEDITED (15-DAY)		OT	CA-ROCHE-1832711		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Ciclosporin			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815016	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131570			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate	S		2 Df, Qd (Dose: 200 Mg)	Sanofi
	Methotrexate	S	Unknown	1 Df, Qw	Not Reported
	Methotrexate	S	Unknown	1 Df, Qw	Not Reported
	Leflunomide	S		1 Df, Qd	Sanofi
	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Enbrel	S		1 Df, Qw	Not Reported
	Actemra	S			Not Reported
	Xeljanz	C			Not Reported
	Sulfasalazine	C			Not Reported
	Wellbutrin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815025	EXPEDITED (15-DAY)		OT	NVSC2020GB043308		50 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dermatomyositis; Disease Progression; Product Use In Unapproved Indication; Pseudomonas Infection; Pulmonary Fibrosis; Skin Ulcer; Treatment Failure	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Azathioprine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	60 Mg		Not Reported
	Prednisolone			S				Not Reported
	Dapsone			S	Unknown	Unk		Not Reported
	Mycophenolate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815046	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602428		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fibromyalgia; Intentional Product Use Issue; Nausea; Oedema; Off Label Use; Rheumatoid Arthritis; Synovitis; Underdose; Vomiting	Rituximab	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Celebrex	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Naproxen	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815068	EXPEDITED (15-DAY)		OT	CA-DRREDDYS-USA/CAN/20/0123276			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Atorvastatin			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Plaquenil			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Alprazolam			C	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Naprosyn			C				Not Reported
	Pantoloc			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815160	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602524		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Blood Pressure Increased; Dermatomyositis; Diarrhoea; Drug Ineffective; Foot Fracture; Infusion Related Reaction; Migraine; Off Label Use; Pain In Extremity; Poor Venous Access; Post-Traumatic Neck Syndrome; Rhinorrhoea; Road Traffic Accident; Thrombophlebitis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Diflucan			C				Not Reported
	Diphenhydramine Hydrochloride			C	Oral			Not Reported
	Euro D			C				Not Reported
	Leucovorin [Folinic Acid]			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C				Not Reported
	Risedronate Sodium			C				Not Reported
	Sulfamethoxazole;Trimipramine			C				Not Reported
	Zoplicone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815187	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598423		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Actemra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not			Not Reported

			otherwise specified)	
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Desoximetasone	C		Not Reported
	Methotrexate	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815201	EXPEDITED (15-DAY)		OT	CA-SA-2020SA114144		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus	Desoximetasone			S	Oral			Sanofi
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Plaquenil			S		400 Mg, Qd		Sanofi
	Arava			S				Sanofi
	Diclofenac Sodium			S		Unk		Not Reported
	Prednisone			S				Not Reported
	Prednisone			S		Unk		Not Reported
	Folic Acid			S		5 Mg, Qd		Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Sulfasalazine			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Pseudoephedrine Hydrochloride			S				Sanofi
	Alendronate Sodium			S				Not Reported
	Cortisone Acetate			S				Not Reported

Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Cetirizine Hydrochloride	S				Not Reported
	Actemra	S				Not Reported
	Cimzia	S				Not Reported
	Cimzia	S				Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	40 Mg, Qd		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole	S				Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S				Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfathalidine	S				Not Reported
	Xeljanz	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815212	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2020-014626			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Ageusia; Arthralgia; Depression; Dna Antibody Negative; Drug Interaction; Fibromyalgia; Gait Disturbance; Liver Function Test Abnormal; Migraine; Nausea; Panic Attack; Paraesthesia; Psoriasis; Psoriatic Arthropathy; Respiratory Syncytial Virus Infection; Sleep Disorder; Suicidal Ideation; Systemic Lupus Erythematosus; Tachyarrhythmia; Type 1 Diabetes Mellitus; Urinary Tract Infection; Viral	Prednisolone			S	Unknown			Bausch And Lomb
	Glyceryl Trinitrate			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Colecalciferol			S	Unknown			Not Reported
	Ezetimibe			S	Unknown			Not Reported
	Ivabradine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported
	Prasugrel			S	Unknown			Not Reported
	Ramipril			S	Unknown			Not Reported

Tonsillitis	Reboxetine		S	Unknown	Not Reported
	Sildenafil		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Topiramate		S	Unknown	Not Reported
	Endone		S	Unknown	Not Reported
	Glucagen		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Mirena		S	Unknown	Not Reported
	Novorapid		S	Unknown	Not Reported
	Oxycontin		S	Unknown	Not Reported
	Rosuvastatin		S	Unknown	Not Reported
	Humira		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815228	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599760		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alanine Aminotransferase Increased; Alopecia; Anxiety; Arthralgia; Aspartate Aminotransferase Increased; Asthenia; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Off Label Use; Pain; Red Blood Cell Sedimentation	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown	9.0 Years		Not Reported

Rate Increased; Rheumatoid Arthritis; Synovitis; Treatment Failure	Methotrexate	S	Unknown	9.0 Years	Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	3.0 Months	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	12.0 Months	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral	2.0 Months	Not Reported
	Xeljanz	S	Oral	2.0 Months	Not Reported
	Xeljanz	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Cetirizine Hydrochloride	C	Unknown		Not Reported
	Cortisone	C	Unknown		Not Reported
	Desoximetasone	C			Not Reported
	Dexamethasone	C	Unknown		Not Reported
	Gabapentin	C	Unknown		Not Reported
	Paracetamol	C	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815260	EXPEDITED (15-DAY)		DS, OT	CA-SAKK-2020SA115119AA		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Live Birth; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Desoximetasone	S			Sanofi
	Desoximetasone	S			Sanofi
	Desoximetasone	S	Oral	Unk	Sanofi
	Cortisone Acetate	S	Oral		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Diclofenac Sodium	S			Not Reported
	Topicort	S	Subcutaneous		Sanofi
	Topicort	S			Sanofi
	Topicort	S	Oral	Unk	Sanofi
	Prednisone	S			Not Reported
	Arava	S	Oral	20 Mg	Sanofi
	Arava	S	Oral	Unk	Sanofi
	Cetirizine Hydrochloride	S		10 Mg	Not Reported
	Cetirizine Hydrochloride	S		20 Mg	Not Reported
	Cetirizine Hydrochloride	S			Not Reported
	Folic Acid	S	Oral	1 Mg	Not Reported
	Folic Acid	S	Oral	5 Unk	Not Reported
	Folic Acid	S		1 Unk	Not Reported
	Folic Acid	S		5 Unk	Not Reported
	Alendronate Sodium	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Qd	Sanofi
	Hydroxychloroquine	S		400 Unk	Sanofi
	Hydroxychloroquine	S		Unk	Sanofi
	Hydroxychloroquine Sulfate	S		400 Mg, Qd	Sanofi
	Hydroxychloroquine Sulfate	S	Oral	40 Unk	Sanofi
	Hydroxychloroquine Sulfate	S	Oral	Unk	Sanofi
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Mg, Qd	Sanofi
	Methotrexate	S	Oral	25 Mg	Not Reported
	Methotrexate	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S		Unk	Not Reported

Methotrexate	S	Oral	25 Mg, Qd	Not Reported
Methotrexate	S	Intra-arterial	25 Unk	Not Reported
Paracetamol	S			Not Reported
Plaquenil	S		400 Mg, Qd	Sanofi
Plaquenil	S		40 Unk	Sanofi
Plaquenil	S	Oral	40 Unk	Sanofi
Prednisone	S			Not Reported
Prednisone	S			Not Reported
Sarilumab	S			Sanofi
Sulfasalazine	S	Oral	1 G, Qd	Not Reported
Sulfasalazine	S	Oral	500 Mg	Not Reported
Leflunomide	S	Oral		Sanofi
Leflunomide	S	Oral		Sanofi
Pseudoephedrine Hydrochloride	S			Sanofi
Pseudoephedrine Hydrochloride	S		25 Mg	Sanofi
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Methotrexate Sodium	S	Subcutaneous		Not Reported
Methotrexate Sodium	S	Oral	25 Mg	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S			Not Reported
Cimzia	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	4 Mg	Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Phthalylsulfathiazole	S			Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported

Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S				Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Simponi	S	Intravenous (not otherwise specified)	Unk		Not Reported
Stelara	S				Not Reported
Sulfathalidine	S				Not Reported
Sulfathalidine	S	Subcutaneous	Unk		Not Reported
Tofacitinib Citrate	S	Subcutaneous			Not Reported
Tofacitinib Citrate	S		Unk		Not Reported
Xeljanz	S				Not Reported
Cortisone Acetate	S	Topical	25 Mg		Not Reported
Acetaminophen	S				Not Reported
Reactine [Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride]	S		10 Mg		Not Reported
Reactine [Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride]	S		20 Unk		Not Reported
Atasol [Paracetamol]	C				Not Reported
Salazopyrin	C				Not Reported
Tofacitinib Citrate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815323	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602209		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition Aggravated; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported

Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815461	EXPEDITED (15-DAY)		DE, OT	CA-ROCHE-2600163		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sepsis; Synovitis; Terminal State; Thrombosis	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S		Not Reported
	Doxycycline	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Simponi	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815481	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1237783		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Osteoporotic Fracture; Spinal Compression Fracture	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815499	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600237			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815502	EXPEDITED (15-DAY)		HO	CA-ROCHE-2600347			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Alopecia	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815592	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597636			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Off Label Use; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Actemra	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Bifidobacterium Bifidum	C	Unknown	Not Reported
	Loperamide	C	Oral	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815625	EXPEDITED (15-DAY)		DE	MX-ADVANZ PHARMA-202005005423			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		200 Mg, Bid(Q12h)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Ceftriaxone Sodium			C				Not Reported
	Clarithromycin			C				Not Reported
	Oseltamivir Phosphate			C				Not Reported
	Methylprednisolone			C				Not Reported
	Norepinephrine			C				Not Reported
	Meropenem			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815637	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597966			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815690	DIRECT	Y	LT			93 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Therapy Cessation	Hydroxychloroquine Sulfate			S	Oral			Sandoz
	Acetaminophen 650 Mg			C				Not Reported
	Albuterol Mdi			C				Not Reported
	Aspirin 81mg			C				Not Reported
	Atorvastatin 10mg			C				Not Reported
	Benzonatate 100 Mg			C				Not Reported
	Finasteride 5mg			C				Not Reported
	Guaifenesin -La 600mg			C				Not Reported
	Heparin 5000 Units			C				Not Reported
	Hydrocodone/Homatropine Syrup			C				Not Reported
	Metoprolol Succinate 100 Mg			C				Not Reported
	Morphine 1 Mg Ivp			C				Not Reported

	Tamsulosin 0.4mg	C	Not Reported
	Piperacillin/Tazobactam 3.375 Gm Ivpb	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815692	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184306			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rash	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Citalopram Hydrobromide			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Mirtazapine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815728	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600346			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Xeljanz	C		Not Reported
	Simponi	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815756	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0739		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Kineret			S				Not Reported
	Actemra			S				Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Desoximetasone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815825	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598500		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive	Actemra			S	Unknown			Not Reported

Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Off Label Use; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Apo-Leflunomide	S	Oral			Not Reported
	Arava	S	Oral			Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Leflunomide	S	Unknown	10 Mg		Not Reported
	Methotrexate	S	Oral	1 Every 1 Weeks		Not Reported
	Methotrexate	S	Unknown	1 Every 1 Days		Not Reported
	Orencia	S	Unknown			Not Reported
	Phthalylsulfathiazole	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown	2 Every 1 Days		Not Reported
	Prednisone	C	Oral	1 Every 1 Days		Not Reported
	Prednisone	C	Oral	1 Every 1 Days		Not Reported
	Xeljanz	C	Unknown	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815846	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597354			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815847	NON-EXPEDITED			NVSC2020US140199			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urticaria	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	200 Mg, Unknown		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815890	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2597924			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gammagard			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Subcutaneous	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Not Reported
	Triamcinolone Acetonide	S		Not Reported
	Triamcinolone Acetonide	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815918	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600989		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Methotrexate			S	Subcutaneous			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815953	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600622		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm Malignant; Off Label Use;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Onychoclasis; Synovitis; Tooth Loss	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous	Not Reported
	Zostavax	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815968	EXPEDITED (15-DAY)		DS	CA-ROCHE-2599481		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Benign Neoplasm; Bladder Operation; Disability; Drug Ineffective; Fatigue; Headache; Influenza Like Illness; Malaise; Off Label Use; Peripheral Swelling; Spinal Pain; Urinary Tract Infection; Vaginal Haematoma	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	6.0 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	105.0 Days		Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported
	Ergocalciferol			C	Oral			Not Reported

	Humira	C	Subcutaneous	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816129	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602954		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Off Label Use; Therapeutic Product Effect Decreased	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Arava			C	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816143	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1238595		61 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Electrocardiogram Qt Prolonged	Amoxicilline Trihydratee		S	Oral	Teva
	Clavulanique (Acide)		S	Oral	Not Reported
	Plaquenil		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816150	EXPEDITED (15-DAY)		OT	CA-ROCHE-2603071		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Incorrect Route Of Product Administration; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Kevzara			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Tofacitinib Citrate	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Rabeprazole Sodium	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816368	EXPEDITED (15-DAY)		DS	CA-ROCHE-2600951		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816376	EXPEDITED (15-DAY)		HO	CA-ROCHE-2598424		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin;	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Necrosis; Skin Ulcer	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816378	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1237799		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Azathioprine			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Tacrolimus	S	Unknown	6 Dosage Forms Daily;		Not Reported
Tacrolimus	S	Unknown	5 Dosage Forms Daily;		Not Reported
Prednisone	C	Oral	17 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816424	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238080			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816425	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238156		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm	Azathioprine			S	Unknown			Not Reported

Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Minocycline	S	Unknown	Actavis
	Methotrexate	S	Subcutaneous	Barr
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816433	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600223		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Endocervical			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Prednisone		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816694	EXPEDITED (15-DAY)		HO	CA-ROCHE-2601297		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Rituximab			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816728	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2020202244		73 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Off Label Use; Product Use Issue	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported
	Inhixa			C	Subcutaneous	40 Mg		Not Reported
	Sirtap			C	Intravenous (not otherwise specified)	2 G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816729	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020200441		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Tazocilline			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816748	EXPEDITED (15-DAY)		OT	NVSC2020GB054189		29 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Drug Ineffective; Transient Ischaemic Attack; Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S				Novartis
	Hydroxychloroquine			S				Novartis
	Clopidogrel			S	Unknown	Unk		Not Reported
	Apixaban			S	Unknown	Unk		Not Reported
	Rivaroxaban			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported
	Warfarin			S				Not Reported
	Atorvastatin			S	Unknown	High Dose		Not Reported
	Atorvastatin			S				Not Reported
	Atorvastatin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816759	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601313			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816805	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020202843		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthritis; Blood Glucose Abnormal; Cataract; Dizziness; Ear Discomfort; Erythema; Fatigue; Headache; Hypotension; Inappropriate Schedule Of Product Administration; Joint Stiffness; Muscle Spasms; Nausea; Rheumatoid Arthritis; Vomiting	Atorvastatin Calcium			S	Unknown	10.0 Mg, 1x/Day		Pfizer
	Bisoprolol			S	Unknown	2.5 Mg, 2x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg		Not Reported
	Sandostatin			S	Intramuscular	30 Mg, Monthly		Not Reported
	Sandostatin			S	Intramuscular	20 Mg 4 Every 1 Week		Not Reported
	Sandostatin			S	Subcutaneous	50 Ug Total		Not Reported
	Sandostatin			S	Intramuscular	30 Mg, Monthly		Not Reported
	Dapagliflozin Propanediol Monohydrate			C	Unknown	5.0 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816921	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1238603		26 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Valve Incompetence; Asthenia; Chest Discomfort; Drug Ineffective; Dyspnoea; Headache; Heart Rate Increased; Hyperhidrosis; Left Ventricular Dilatation; Myocarditis; Nausea;	Azathioprine			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Oral	2000 Milligram Daily;		Teva
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Acetylsalicylic Acid			C	Unknown	81 Milligram Daily;		Not Reported
	Colchicine			C	Unknown	.6 Milligram Daily;		Not Reported

Nephritis; Pleuritic Pain; Systemic Lupus Erythematosus; Treatment Failure; Vasculitis	Naproxen		C	Unknown	500 Milligram Daily;	Not Reported
	Prednisone		C	Unknown	50 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816922	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238103		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	2.8571 Milligram Daily; 40 Mg, 1 Every 2 Weeks		Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816944	EXPEDITED (15-DAY)		HO	CA-ROCHE-2600620			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Medication Error; Musculoskeletal Disorder; Off Label Use; Synovitis;	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Azathioprine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816994	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1047833		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Off Label Use	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Azithromycin			S				Not Reported
	Azithromycin			S				Not Reported
	Hidroxicloroquina /00072601/			S	Oral	400 Mg Dia		Mylan
	Hidroxicloroquina /00072601/			S				Mylan
	Hidroxicloroquina /00072601/			S				Mylan
	Anakinra			S	Subcutaneous	100 Milligram		Mylan
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg Dia		Mylan
	Tocilizumab			S				Mylan
	Tocilizumab			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817025	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA128122		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypersensitivity;	Leflunomide			S	Unknown	Unk		Sanofi
	Codeine			S	Unknown	Unk		Not Reported
	Alendronate Sodium			S	Unknown	70 Mg, 1 Every 1 Week		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Methotrexate			S	Unknown	12 Mg, 1 Every 1 Week		Not Reported

Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Necrosis; Skin Ulcer	Methotrexate	S	Unknown	12 Mg	Not Reported
	Methotrexate	S	Unknown	12.5 Mg	Not Reported
	Methotrexate	S	Unknown	12.5 Mg, 1 Every 1 Week	Not Reported
	Methotrexate	S	Unknown	10 Mg, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, 1 Every 1 Week	Not Reported
	Methotrexate	S	Unknown	10 Mg, 1 Every 1 Week	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, Qm	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Mg, 1 Every 1 Week	Not Reported
	Humira	S	Subcutaneous	40 Mg, 1 Every 2 Weeks	Not Reported
	Orencia	S	Unknown	780 Mg, 1 Every 1 Week	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, 2 Every 1 Day	Not Reported
	Actemra	S	Unknown	680 Mg, 1 Every 4 Weeks	Not Reported
	Actemra	S	Unknown	360 Mg, 1 Every 1 Month	Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817030	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202004004686			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pharyngitis; Sinus Disorder	Hydroxychloroquine			S	Unknown	200 Mg		Concordia
	Xeljanz			S	Oral	5 Mg, Bid (5mg 1 Tablet By Mouth Twice A Day)		Not Reported
	Xeljanz			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817236	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200505926		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Synovitis; Throat Tightness	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Supeudol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817261	EXPEDITED (15-DAY)		HO	CA-ROCHE-2603030		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Contraindicated Product Administered	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Gabapentin			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown	Extended Release		Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Aclasta	C	Intravenous (not otherwise specified)		Not Reported
	Diphenoxylate Hydrochloride	C	Unknown		Not Reported
	Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Loperamide Hydrochloride	C	Unknown		Not Reported
	Nasonex	C	Unknown	Metered Dose	Not Reported
	Oxycodone Terephthalate	C			Not Reported
	Pantoprazole Magnesium	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Risedronate Sodium	C	Unknown		Not Reported
	Trazodone Hydrochloride	C	Oral		Not Reported
	Tylenol	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817265	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605594			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817283	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1050069		81 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Vomiting	Lopinavir/Ritonavir			S	Oral	1 Dosage Form, Bid		Not Reported
	Naloxone/Oxycodone			S	Oral	10 Milligram, Bid		Not Reported
	Hidroxicloroquina /00072601/			S	Oral	Unk		Mylan
	Prolia			C	Subcutaneous	Unk		Mylan
	Stilnox			C	Oral	10 Milligram, Qd		Mylan
	Pantoprazol /01263201/			C	Oral	20 Milligram, Qd		Mylan
	Calcium Carbonate W/Colecalciferol			C	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817285	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1237763			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817287	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1237764			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Amoxicillin Trihydrate;Clavulanate Potassium			C	Unknown			Not Reported
	Amoxil [Amoxicillin]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817367	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1051084		77 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Injury; Off Label Use; Pruritus; Purpura; Rash	Azithromycin			S	Oral	1 Dosage Form, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	400 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817430	EXPEDITED (15-DAY)		DE	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-051273			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy	Azithromycin			S	Oral	500 Milligram		Zydus Pharm
	Hydroxychloroquine			S	Oral	400 Milligram		Not Reported
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Milligram		Not Reported
	Enoxaparin			S	Subcutaneous	40 Milligram		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab			S				Not Reported
	Dexketoprofen			S	Intravenous (not otherwise specified)	25 Milligram Every 8 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817482	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601342		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Off Label Use; Synovitis; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab;Vorhyaluronidase Alfa			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Amitriptyline	C	Unknown	Not Reported
	Amitriptyline Hydrochloride	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Calcium Carbonate	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Elavil [Amitriptyline Hydrochloride]	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Imitrex [Sumatriptan]	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817551	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1238086		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Depressed Mood; Disability; Exposure During Pregnancy; Hand Deformity; Inappropriate Schedule Of Product Administration; Inflammation; Limb Discomfort; Memory Impairment; Movement Disorder; Musculoskeletal Stiffness; Nasopharyngitis; Peripheral Swelling	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Aamitriptyline			C	Unknown	10 Milligram Daily;		Not Reported
	Azithromycin			C	Unknown			Not Reported
	Domperidone			C	Unknown			Not Reported
	Esomeprazole Sodium			C	Unknown			Not Reported
	Gabapentin			C	Unknown	400 Milligram Daily;		Not Reported
	Metonia			C	Unknown			Not Reported
	Prednisone			C	Unknown	8 Milligram Daily;		Not Reported

	Ranitidine	C	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817558	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238074		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817621	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238124			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use; Prescribed Underdose; Product Use Issue	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817630	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201711-006337			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Hydroxychloroquine			S	Oral	400 Mg, Freq: Unk X 1 Days		Concordia
	Leflunomide			S	Oral	20 Mg, Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	50 Mg, Unk		Not Reported
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qd		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Apo Lefunomide			S	Unknown	20 Mg, Freq: Unk X 1 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Meloxicam			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817647	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238602		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Minocycline Hydrochloride			S	Unknown			Actavis
	Minocycline Hydrochloride			S	Unknown			Actavis
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Amoxicillin Sodium;Clavulanate Potassium			C	Unknown			Not Reported
	Amoxil [Amoxicillin]			C	Unknown			Not Reported
	Bacillus Calmetteguerin Bcg			C	Unknown			Not Reported
	Bacillus Calmetteguerin Bcg			C	Intravenous (not otherwise specified)			Not Reported

	Leflunomide	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817829	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238072		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Parenteral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817869	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238148			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Headache; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Stomatitis; Tinnitus; Treatment Failure	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817873	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238139			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Off Label Use; Product Use Issue; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Azathioprine			S	Oral	200 Milligram Daily;		Not Reported
	Leucovorin Calcium			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Depo-Medrol With Lidocaine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	400 Milligram Daily;		Not Reported
	Ketoprofen			S	Topical			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prevnar 13			S	Intramuscular			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817875	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238166			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Polyarthritis; Synovitis; Weight Decreased	Azathioprine			S	Unknown			Not Reported
	Mycophenolate Sodium			S	Unknown			Teva
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S				Not Reported
	Acetaminophen			C	Oral			Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Actemra			C	Unknown			Not Reported
	Bisoprolol			C				Not Reported
	Candesartan			C				Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported
	Folic Acid			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Oral			Not Reported
	Sulfamethoxazole And Trimethoprim			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817915	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1239120		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Malaise; Throat Cancer; Thrombosis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Prednisone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17818373	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1237765			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17818454	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601993		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Therapeutic Product Effect Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Lyrica	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17818465	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238099			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17818499	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1239114		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Drug Ineffective; Gastric Ulcer; Malaise; Throat Cancer; Thrombosis	Azathioprine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Barr
	Mycophenolate Mofetil	S	Unknown	Teva
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tacrolimus	S	Oral	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17818723	NON-EXPEDITED			NVSC2020US141219			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Iron Overload	Jadenu			S	Unknown	Unk		Novartis
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17818940	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602354		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 2.0 Years		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17818965	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605839		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	12304140	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-1745534			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown	25 Mbq		Not Reported

Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown	And 5 Mg	Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral	25 Mg (For 11 Years)	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	11 Months	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Alendronate Sodium	S	Oral		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported

	Golimumab	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Kevzara	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Paracetamol	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Stelara	S	Unknown	Not Reported
	Topicort [Desoximetasone]	S	Cutaneous	Not Reported
	Topicort [Desoximetasone]	S		Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Salazopyrin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17042389	EXPEDITED (15-DAY)		OT	CA-ROCHE-2464645		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Infliximab	S	Unknown			Not Reported
Orencia	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
Simponi	S	Subcutaneous	Solution		Not Reported
Sulfasalazine	S	Oral			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Desoximetasone	C	Unknown			Not Reported
Methotrexate	C	Oral			Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17063042	EXPEDITED (15-DAY)		OT	CA-ROCHE-2471629			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17721471	EXPEDITED (15-DAY)		LT	FR-TEVA-2020-FR-1227414		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Azithromycine Anhydre			S	Oral	250 Milligram		Not Reported
	Plaquenil 200 Mg, Comprime Enrobe			S	Oral	2-3 Cp Per Day:400 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17804815	EXPEDITED (15-DAY)		DE, OT	ES-ABBVIE-20K-144-3410200-00		86 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depressed Mood; Hypertransaminasaemia; Long Qt Syndrome	Kaletra			S	Oral			Not Reported
	Hidroxicloroquina			S	Unknown			Not Reported
	Azitromicina			S	Unknown			Not Reported
	Metilprednisolona			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17818370	EXPEDITED (15-DAY)		OT	CA-ROCHE-2603021			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Gait Disturbance; Pain	Rituxan	S	Intravenous drip	Not Reported
	Cellcept [Mycophenolate Mofetil]	S	Unknown	Not Reported
	Ceftazidime	S	Unknown	Not Reported
	Piperacillin/Tazobactam	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rosuvastatin	S	Unknown	Not Reported
	Vancomycin	S	Unknown	Not Reported
	Lasix [Furosemide]	S	Unknown	Not Reported
	Pantoprazole	C		Not Reported
	Acetaminophen	C		Not Reported
	Actonel	C		Not Reported
	Amiodarone	C	Unknown	Not Reported
	Diphenhydramine	C		Not Reported
	Eprex	C	Intravenous (not otherwise specified)	Not Reported
	Escitalopram	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Insulin Lispro	C		Not Reported
	Januvia	C		Not Reported
	Metformin	C	Unknown	Not Reported
	Methylprednisolone	C		Not Reported
	Metoprolol	C		Not Reported
	Pantoloc [Pantoprazole]	C		Not Reported
	Piperacillin/Tazobactam	C		Not Reported
	Potassium Chloride	C		Not Reported
	Risedronate Sodium	C		Not Reported
	Slow-K	C		Not Reported
	Tylenol	C		Not Reported
	Ventolin [Salbutamol]	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17818429	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601015			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Off Label Use; Pain; Peripheral Swelling; Rash; Skin Ulcer	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17818446	EXPEDITED (15-DAY)		HO	CA-ROCHE-2602195		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Off Label Use; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Disorder; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Naprosyn [Naproxen]	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17818450	EXPEDITED (15-DAY)		OT	CA-ROCHE-2603092			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatomyositis; Dysphagia; Gastrointestinal Disorder; Hepatitis; Muscle Disorder; Skin Disorder	Cellcept [Mycophenolate Mofetil]			S	Unknown	Therapy Duration: 61.0		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myfortic			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17818458	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601809		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Arthralgia; Chronic Sinusitis; Diverticulum; Drug Ineffective; Haemochromatosis; Impaired Work Ability; Irritable Bowel Syndrome; Joint Swelling; Nausea; Osteoporosis; Treatment Failure	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17818807	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3414053-00		77 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Off Label Use	Kaletra			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Zitromax Avium			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17818844	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598521		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wheezing	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17818879	EXPEDITED (15-DAY)		HO	CA-ROCHE-2605911			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Azathioprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17818888	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601616		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cartilage Atrophy; Drug Ineffective; Joint Swelling; Nausea; Nephrotic Syndrome; Off Label Use; Periorbital Oedema; Renal Disorder; Skin Erosion; Therapeutic Product Effect Decreased; Wrist Deformity	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Leflunomide			C				Not Reported
	Naproxen			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17819004	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601685			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Goitre; Headache; Inflammation; Joint Swelling; Knee Arthroplasty; Lower Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

Arthritis; Swelling	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17819012	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601843			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe Solution Subcutaneous		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17819015	EXPEDITED (15-DAY)		HO	CA-ROCHE-2598559		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Multiple Fractures; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17819081	EXPEDITED (15-DAY)		OT	CA-ROCHE-1895764			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Bacitracin	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Neomycin Sulfate	S	Unknown	Not Reported
	Polymyxin B Sulfate	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17819232	EXPEDITED (15-DAY)		OT	BN-ACCORD-182780		67 YR	Male	BRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Hydroxychloroquine			S		400 Mg Twice Daily Day-1 And 200 Mg Twice Daily Day-2 To 5		Not Reported
	Lopinavir/Ritonavir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17819257	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599836		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Cough; Drug Ineffective; Headache; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Viral Infection	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17819264	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602945			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17819335	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202004005747			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Pain In Extremity; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Unk, Citrate Free (1 In 2 Wk)		Not Reported
	Methotrexate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17819381	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1239130			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S				Barr
	Minocycline			S	Unknown			Actavis
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17819383	EXPEDITED (15-DAY)		DS	CA-ROCHE-2601269		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis; Gait	Actemra			S	Intravenous (not			Not Reported

Disturbance; Multiple System Atrophy; Off Label Use; Rheumatoid Arthritis			otherwise specified)	
	Rituximab	S	Intravenous drip	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Oral	Not Reported
	Xeljanz	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17819384	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601291		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported

Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Fosamax	S	Oral	Not Reported
Fosamax	S		Not Reported
Folic Acid	S	Unknown	Not Reported
Diclofenac Sodium	S	Unknown	Not Reported
Arava	S	Oral	Not Reported
Cetirizine	S	Unknown	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Desoximetasone	S	Oral	Not Reported
Certolizumab Pegol	S	Subcutaneous	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Fosamax	S	Intracavernous	Not Reported
Fosamax	S		Not Reported
Fosamax	S	Unknown	Not Reported
Fosamax	S		Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S		Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17819386	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606795		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Rabeprazole Sodium			C	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2020	17350897	EXPEDITED (15-DAY)		DE	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-00		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Chest Discomfort	Atrovent	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Flovent	S	Unknown	Not Reported
	Albuterol Sulfate And Ipratropium Bromide	S	Unknown	Not Reported
	Lasix [Furosemide Sodium]	S	Unknown	Not Reported
	Lipitor	S	Unknown	Not Reported
	Losec [Omeprazole Magnesium]	S	Oral	Not Reported
	Metformin	S	Oral	Not Reported
	Nitrazadon	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Salmeterol Xinafoate	S	Unknown	Not Reported
	Tylenol	S	Unknown	Not Reported
	Atorvastatin Calcium	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2020	17819810	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605534		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Off Label Use; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2020	17819817	EXPEDITED (15-DAY)		HO	CA-ROCHE-2599451			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Movement Disorder; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomadesis; Onychomycosis	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	12855891	EXPEDITED (15-DAY)		HO	CA-ROCHE-1842514		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Naproxen			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral	Therapy Duration: 6 Days		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cosentyx			S	Subcutaneous			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 731.0		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 731.0		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	13161522	EXPEDITED (15-DAY)		DS, HO, OT	CA-CELGENEUS-CAN-2016047597		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Arthralgia; Arthritis; Arthritis; Arthropathy; Aspartate Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Creatinine Increased; Blood Parathyroid Hormone Decreased; Blood Pressure Systolic Increased; C-Reactive Protein Abnormal; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Decreased Appetite; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Enthesopathy; Erythema; Erythema; Erythema; Fatigue; Fear Of Injection; General Physical Health Deterioration; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity;	Otezla			S	Oral	60 Milligram		Celgene
	Otezla			S	Oral	60 Milligram		Celgene
	Otezla			S	Oral			Celgene
	Otezla			S	Oral	120 Milligram		Celgene
	Otezla			S	Oral			Celgene
	Otezla			S	Oral			Celgene
	Adalimumab			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Ciclosporin			S	Oral	.6 Milligram		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Golimumab			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous drip	400 Milligram		Not Reported
	Sulfasalazine			S	Endocervical			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Hypersensitivity; Inflammation; Infusion Related Reaction; Insomnia; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Ustekinumab	S	Subcutaneous		Not Reported
	Ustekinumab	S	Unknown		Not Reported
	Abatacept	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	25 Milligram	Not Reported
	Enbrel	S	Unknown	25 Milligram	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Sulfamethoxazole	S	Oral	600 Milligram	Not Reported
	Motrin	S	Oral	600 Milligram	Not Reported
	Motrin	S	Oral	6 Dosage Forms	Not Reported
	Motrin	S	Oral	600 Milligram	Not Reported
	Motrin	S	Oral	600 Milligram	Not Reported
	Motrin	S	Oral	600 Milligram	Not Reported
	Motrin	S	Oral	600 Milligram	Not Reported
	Motrin	S	Oral		Not Reported
	Alendronate Sodium	S	Unknown	70 Milligram	Not Reported
	Arava	S	Unknown	20 Milligram	Not Reported
	Celebrex	S	Oral	200 Milligram	Not Reported
	Codeine	S	Unknown		Not Reported
	Cosentyx	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Remicade	S	Intravenous drip		Not Reported

Rituximab	S	Intravenous drip	2000 Milligram	Not Reported
Rituximab	S	Unknown		Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous	15 Milligram	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram	Not Reported
Methotrexate	S	Oral	4 Dosage Forms	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram	Not Reported
Apo Ibuprofen	S	Oral	600 Milligram	Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Colchicine	C	Oral	.6 Milligram	Not Reported
Folic Acid	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Methotrexate Sodium	C	Oral	4.0 Dosage Forms	Not Reported
Methotrexate Sodium	C	Unknown	10 Milligram	Not Reported
Methotrexate Sodium	C	Oral		Not Reported
Methotrexate Sodium	C	Unknown	2.5 Milligram	Not Reported
Mogadon	C	Unknown	5 Milligram	Not Reported
Oxyneo	C	Oral	40 Milligram Er	Not Reported
Oxyneo	C	Oral	10 Milligram	Not Reported
Oxyneo	C	Unknown	40 Milligram Er	Not Reported
Oxyneo	C	Unknown	10 Milligram	Not Reported
Oxyneo	C	Unknown	10 Milligram	Not Reported
Uloric	C	Oral	160 Milligram	Not Reported
Uloric	C	Oral	80 Milligram	Not Reported
Uloric	C	Unknown	80 Milligram	Not Reported
Uloric	C	Unknown		Not Reported
Oxycodone Hydrochloride	C	Unknown	40 Milligram	Not Reported

Oxycodone Hydrochloride	C	Unknown	10 Milligram		Not Reported
Oxycodone Hydrochloride	C	Unknown			Not Reported
Febuxostat	C	Unknown	160 Milligram		Not Reported
Nitrazepam	C	Unknown			Not Reported
Nitrazepam	C	Unknown			Not Reported
Nitrazepam	C	Unknown	5 Milligram		Not Reported
Nitrazepam	C	Unknown			Not Reported
Dexilant	C	Unknown			Not Reported
Gravol	C	Unknown			Not Reported
Benadryl	C	Unknown			Not Reported
Acide Folique	C	Unknown			Not Reported
Actonel	C	Oral	35 Milligram		Not Reported
Naproxen	C	Unknown	500 Milligram		Not Reported
Oxycodone	C	Unknown	10 Milligram		Not Reported
Oxycodone	C	Unknown	40 Milligram		Not Reported
Oxycodone	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported
Vitamin D3	C	Oral	2000 Iu (International Unit)		Not Reported
Xeljanz	C	Unknown			Not Reported
Cannabis Sativa	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	13182650	EXPEDITED (15-DAY)		OT	CA-ROCHE-1747445		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Viral Upper Respiratory Tract Infection	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Xeljanz	C	Oral	On Hold	Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	14763969	EXPEDITED (15-DAY)		OT	CA-ROCHE-2104641		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Vaccine; Condition Aggravated; Diarrhoea; Drug Ineffective; Fall; Hypersensitivity; Laryngeal Disorder; Larynx Irritation; Nausea; Product Use Issue; Pruritus; Treatment Failure; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	15237821	EXPEDITED (15-DAY)		CA, DE	DE-ROCHE-2162345			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Ezetimibe			S	Transplacental	From Gestational Week 0-14		Not Reported
	Clexane			S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 200 Mg, Frequency: Once Daily From		Not Reported
	Heparin Lmw			S	Transplacental			Not Reported
	Xarelto			S	Transplacental	From Gestational Week 0-5		Not Reported
	Hydroxychloroquine			S	Transplacental	From Gestational Week 0-14		Not Reported
	Acetylsalicylic Acid			S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 100 Mg, Frequency: Once Daily100 Mg		Not Reported
	Enoxaparin			S	Transplacental	From Gestational Week 0-14		Not Reported
	Nicotine			S	Transplacental	From Gestational Week 0-14		Not Reported
	Ramipril			S	Transplacental	From Gestational Week 0-113+6		Not Reported
	Prednisolon [Prednisolone]			S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 10 Mg, Frequency: Every 2 Days From		Not Reported

Tacrolimus	S	Transplacental	From Gestational Week 0-14	Not Reported
Tacrolimus	S			Not Reported
Pantozol [Pantoprazole Sodium Sesquihydrate]	S	Transplacental	From Gestational Week 0-14therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 40 Mg, Fr	Not Reported
Quensyl	S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 400 Mg, Frequency: Once Daily	Not Reported
Salbutamol	S	Transplacental	Frequency: Daily From Gestational Week 0-14	Not Reported
Aliskiren	S	Transplacental		Not Reported
Rituximab	S	Transplacental		Not Reported
Rasilez	S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 17/Jan/2012 Dose: 300 Mg, Frequency: Once Daily	Not Reported
Metamizole	S	Transplacental	From Gestational Week 0-14	Not Reported
Dalteparin Sodium	S	Transplacental		Not Reported
Novaminsulfon	S	Transplacental		Not Reported
Delix [Ramipril]	S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 20 Mg, Frequency: Once Daily	Not Reported
Torem [Torasemide]	S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date:	Not Reported

				20/Mar/2012 Dose: 100 Mg, Frequency: Once Daily From	
	Advagraf	S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 6 Mg, Frequency: Once Daily	Not Reported
	Simvastatin	S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 From Gestational Week 0-14	Not Reported
	Cytotec	C	Transplacental	Start Date And Cessation Date: 20/Mar/2012	Not Reported
	Cyclophosphamide	C	Transplacental	3000 Mg Cumulative Start Date, Cessation Date: /Aug/2011	Not Reported
	Mifegyne	C	Transplacental	Start Date And Cessation Date: 20/Mar/2012	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	15247879	EXPEDITED (15-DAY)		DE, HO	CA-ROCHE-2164538		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Photosensitivity Reaction; Product Use In Unapproved Indication; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stomatitis; Thrombosis; Urticaria	Sulfasalazine	S		Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S	Intravenous (not otherwise specified)	Not Reported
	Ilaris	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported

	Cannabis Sativa	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Minocycline	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Oxyquinoline Sulfate	S	Unknown	Not Reported
	Oxyquinoline Sulfate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Lyrica	C		Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	16808742	EXPEDITED (15-DAY)		OT	CA-ROCHE-2402077		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Sulfasalazine	C		Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17317853	EXPEDITED (15-DAY)		OT	CA-ROCHE-2529157		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Hypersensitivity; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Acetaminophen;Codeine Phosphate			C				Not Reported
	Atacand			C	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Hydrodiuril			C				Not Reported
	Neurontin			C	Unknown			Not Reported
	Premarin			C				Not Reported

	Tylenol	C	Unknown		Not Reported
	Acetaminophen	C			Not Reported
	Aluminium Acetate	C			Not Reported
	Benzethonium Chloride	C			Not Reported
	Ergocalciferol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17746062	EXPEDITED (15-DAY)		LT	FR-PFIZER INC-2020178143		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	250 Mg, 1x/Day		Pfizer
	Nivaquine [Chloroquine Sulfate]			S	Oral	200 Mg, Daily (2-3 Tablets Per Day)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, Daily, 2-3 Tablets Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17756593	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010455			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Mg, Q.Wk.		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, (One Every Six Weeks)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, Q.O.Wk.		Not Reported
	Methotrexate			S	Unknown	15 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Intravenous (not	200 Mg, Bid		Not Reported

					otherwise specified)					
	Sulfasalazine			C	Unknown	Unk				Not Reported
	Wellbutrin			C	Unknown	Unk				Not Reported
	Xeljanz			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17772750	EXPEDITED (15-DAY)		HO, LT, OT	FR-PFIZER INC-2020187436		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	500 Mg		Pfizer
	Propranolol			S	Oral	20 Mg, Every 12 Hours		Not Reported
	Laroxyl			S	Oral	15 Drop, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, Every 12 Hours		Not Reported
	Paracetamol			C	Oral	Unk Unk, As Needed		Not Reported
	Pantoprazole			C	Oral	20 Mg, 1x/Day		Not Reported
	Oxygen			C	Respiratory (inhalation)	1 L, Every 1 Minute		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17810040	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005315			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain In Extremity; Pleural Effusion; Rheumatoid Arthritis; Rheumatoid Arthritis; Skin Infection	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17811826	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005312			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Septic Shock	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17811877	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005316			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myocardial Reperfusion Injury	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17811905	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005343			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myocardial Reperfusion Injury	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17814986	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-025966		86 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depressed Mood; Hypertransaminasaemia; Long Qt Syndrome	Azithromycin			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Kaletra			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820055	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601477		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper;	Methotrexate			S	Oral			Not Reported

Bronchitis; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hepatotoxicity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass; Nodule; Off Label Use; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Methotrexate	S	Oral		Not Reported
	Rituximab	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Erythromycin	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Wellbutrin	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Risedronate	C	Unknown		Not Reported
	Risedronate	C	Oral		Not Reported
	Ergocalciferol	C	Unknown	4000 Iu (International Unit)	Not Reported
	Celebrex	C	Unknown		Not Reported
	Celebrex	C	Unknown		Not Reported
	Cannabis Sativa	C	Unknown		Not Reported
	Bupropion	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820092	EXPEDITED (15-DAY)		DS	CA-ROCHE-2601286		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Off Label Use; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Indometacin	S	Unknown	Not Reported
	Indometacin	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Folic Acid	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820095	EXPEDITED (15-DAY)		OT	GB-TEVA-2020-GB-1239435		23 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Encephalitis; Enterovirus Infection; Off Label Use	Prednisolone			S	Unknown			Actavis
	Prednisolone			S	Unknown	In July 2017 At The Time Of Presentation For The 1st Time		Actavis
	Prednisolone			S	Oral	In 2018, At The Time Of Flare Of Sle Administered After Methylprednisolone		Actavis
	Prednisolone			S	Oral	Final Dose After Tapered Down By 5mg/Week		Actavis
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown	In July 2017 At The Time Of Presentation For The 1st Time; Later Discontinued		Not Reported
	Mycophenolate Mofetil			S	Unknown	After Azathioprine Was Stopped; Therapy Stopped In 2018 After 2en Enterovirus Event		Teva
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown	375 Mg/M2 In 2 Doses 14 Days Apart		Not Reported
	Rituximab			S	Other	First Dose: 2g/Kg Body Weight; Second Dose After 2 Weeks: 1g Infusion In 2 Doses 14 Days Apart		Not Reported
	Immunoglobulins Nos			S	Intravenous (not otherwise specified)	2 G/Kg		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)			Not Reported
	Aciclovir			C	Intravenous (not			Not Reported

			otherwise specified)		
	Methylprednisolone	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820175	EXPEDITED (15-DAY)		HO	CA-ROCHE-2602385		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Infection; Limb Discomfort; Off Label Use; Rash; Rheumatoid Arthritis; Urticaria	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			C				Not Reported
	Prednisone			C				Not Reported
	Tofacitinib Citrate			C				Not Reported

	Viread	C	Not Reported
	Amlodipine	C	Not Reported
	Arava	C	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820197	EXPEDITED (15-DAY)		OT	CA-ROCHE-2603590			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Exfoliative Rash; Fatigue; Hepatitis; Myositis; Pruritus; Pyrexia; Swelling; Urticaria; Visual Impairment	Mycophenolate Mofetil			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820205	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600455			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820234	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600299		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Crohn'S Disease; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Gastrointestinal Disorder; Impaired Work Ability; Iron Deficiency Anaemia; Joint Effusion; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Skin Warm; Spinal Stenosis; Therapeutic Product Effect Decreased; Tuberculin Test Positive; Urinary Tract Infection	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Gold			C	Unknown			Not Reported
	Prednisone			C	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820297	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602932		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Fatigue; Glossodynia; Hypersensitivity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Winpred	S	Oral	Not Reported
Diclofenac	C	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820305	EXPEDITED (15-DAY)		DS	CA-ROCHE-1664109		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

Voltaren [Diclofenac]	S	Unknown	Not Reported
Diclofenac	S	Unknown	Not Reported
Diclofenac Potassium	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820341	EXPEDITED (15-DAY)		OT	CA-ROCHE-2167460		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Contraindicated Product Administered; Drug Ineffective; Fatigue; Gastrointestinal Disorder; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820384	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-025850		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome	Azithromycin			S	Unknown	500 Milligram, Once A Day		Aurobindo
	Kaletra			S	Unknown	1 Dosage Form, Two Times A Day		Not Reported
	Interferon Beta			S	Unknown	250 Milligram, Every Other Day		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820447	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-026176		11 YR	Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Infection; Off Label Use; Shock	Azithromycin			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Lopinavir;Ritonavir			S	Oral	Unk		Not Reported
	Methylprednisolone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820507	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600110		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Intentional Product Use Issue; Nausea; Off Label Use; Oral Discomfort; Product Use Issue; Treatment Failure; Uveitis	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Kevzara	S	Unknown	Not Reported
	Kevzara	S		Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Prednisone	C		Not Reported
	Rabeprazole Sodium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820529	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605602			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

	Orencia	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Meloxicam	C	Oral	Not Reported
	Prednisolone	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820530	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599273		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Anakinra			C				Not Reported

Ativan	C	Unknown	Not Reported
Benadryl Cold	C		Not Reported
Codeine	C		Not Reported
Darifenacin	C	Unknown	Not Reported
Desoximetasone	C	Oral	Not Reported
Desoximetasone	C	Intramuscular	Not Reported
Dilaudid	C	Unknown	Not Reported
Dilaudid	C	Unknown	Not Reported
Diphenhydramine	C		Not Reported
Dyclonine Hydrochloride	C		Not Reported
Furosemide	C		Not Reported
Hydromorphone	C		Not Reported
Kadian	C		Not Reported
Kenalog [Triamcinolone Acetonide]	C	Intra-articular	Not Reported
Loperamide	C	Unknown	Not Reported
Morphine Sulphate	C		Not Reported
Norflex [Orphenadrine Citrate]	C		Not Reported
Omnaris	C		Not Reported
Oxyneo	C		Not Reported
Pantoprazole Sodium	C		Not Reported
Plantago Ovata	C		Not Reported
Restasis	C		Not Reported
Synthroid	C		Not Reported
Trimethoprim	C		Not Reported
Urispas	C		Not Reported
Vagifem	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820557	EXPEDITED (15-DAY)		OT	NVSC2020US140984			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Prednisone			S	Transplacental	Maternal Dose: Unknown		Novartis
	Hydroxychloroquine			S	Transplacental	Maternal Dose: Unknown		Not Reported
	Fentanyl			S	Transplacental	Maternal Dose: Unknown		Not Reported

	Lidocaine	S	Transplacental	Maternal Dose: 2 Percent	Not Reported
	Prostacyclin	S	Transplacental	Maternal Dose : Unknown	Not Reported
	Bupivacaine	S	Transplacental	Maternla Dose: Unknown	Not Reported
	Morphine	S	Transplacental	Maternal Dose: Unknown	Not Reported
	Heparin	S	Transplacental	Maternal Dose: Unknown	Not Reported
	Epinephrine	S	Transplacental	Maternal Dose: Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820565	EXPEDITED (15-DAY)		HO	CA-ROCHE-2601432			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Pain; Nausea; Neck Pain; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rash; Therapeutic Product Effect Decreased; Weight Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820577	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600353		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Back Disorder; Condition	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Mouth Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Anakinra	S	Subcutaneous	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820644	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599668		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S				Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported
	Topicorten			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Diclofenac Sodium	S	Unknown		Not Reported
Desoximetasone	S	Unknown		Not Reported
Desoximetasone	S	Oral		Not Reported
Cortisone Acetate	S	Unknown		Not Reported
Cortisone Acetate	S	Oral		Not Reported
Cimzia	S	Subcutaneous		Not Reported
Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Cetirizine Hydrochloride	S	Unknown		Not Reported
Arava	S	Oral		Not Reported
Alendronate Sodium	S	Unknown		Not Reported
Leflunomide	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820691	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020202532		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthritis; Blood Glucose Abnormal; Cataract; Cholelithiasis; Dizziness; Ear Discomfort; Erythema; Facial Neuralgia; Fatigue; Groin Pain; Headache; Hypotension; Inappropriate Schedule Of Product Administration; Joint Stiffness; Labyrinthitis; Muscle Spasms; Nausea; Rheumatoid Arthritis; Visual Impairment; Vomiting	Atorvastatin Calcium			S	Unknown	10 Mg, 1x/Day		Pfizer
	Bisoprolol			S	Unknown	2.5 Mg, 2x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg		Not Reported
	Sandostatin			S	Subcutaneous	Unk		Not Reported
	Sandostatin Lar			S	Intramuscular	30 Mg, Monthly		Not Reported
	Sandostatin Lar			S	Intramuscular	30 Mg, Monthly		Not Reported
	Dapagliflozin Propanediol Monohydrate			C	Unknown	5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820782	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020200464		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820787	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020200440		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Quetiapine Arrow			S	Oral	100 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820788	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2020202119		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Maternal Exposure During Pregnancy; Off Label Use; Product Use In Unapproved Indication; Product Use Issue; Thrombocytopenia	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported
	Folic Acid			C		Unk		Not Reported
	Fer [Ascorbic Acid;Ferrous Chloride]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820792	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020200453		64 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax	S	Oral	250 Mg, 1x/Day	Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	600 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820798	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601806		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Unevaluable Event	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S				Not Reported
	Xeljanz			S	Oral			Not Reported

	Xeljanz	S			Not Reported
	Minocycline Hydrochloride	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820804	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2020202121		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820851	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020202110		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	500 Mg		Pfizer
	Zithromax			S	Oral	250 Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg		Not Reported
	Esidrex			C		Unk		Not Reported
	Rocephine			C		Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			C		Unk		Not Reported
	Diffu K			C		Unk		Not Reported
	Ramipril			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820863	EXPEDITED (15-DAY)		HO	CA-ROCHE-2602973		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastric	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Ulcer; Malaise; Throat Cancer; Thrombosis	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Tacrolimus	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Azathioprine	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17821010	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2020200438		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Ventricular Extrasystoles	Azithromycine Pfizer			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17821037	EXPEDITED (15-DAY)		OT	CA-ROCHE-1957024		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Hypersensitivity; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Malaise; Nausea; Pain In Extremity; Peripheral Swelling	Rituximab			S	Intravenous (not otherwise specified)	Therapy Duration: 7 Months		Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 7 Months		Not Reported
	Methotrexate			S	Subcutaneous	Therapy Duration: 10 Months		Not Reported
	Plaquenil [Hydroxychloroquine			S	Oral	Therapy Duration: 2 Years		Not Reported

Sulfate]					
Prednisone	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Xeljanz	S	Unknown	Therapy Duration: 4 Days		Not Reported
Apo-Prednisone	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Infliximab	S	Intravenous (not otherwise specified)			Not Reported
Infliximab	S				Not Reported
Atorvastatin Calcium	C	Unknown			Not Reported
Pantoprazole Sodium	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17821038	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2020204019		41 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Off Label Use; Product Use In Unapproved Indication	Zitromax Avium			S	Oral	1 Df, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	2 Df, 1x/Day		Not Reported
	Kaletra			S	Oral	4 Df, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17821065	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599160		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gingival Bleeding; Headache; Liver Function Test Increased; Syncope	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)	
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Prednisone	C		Not Reported
	Prevacid	C		Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17821119	EXPEDITED (15-DAY)		OT	US-HORIZON-PRE-0167-2020			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Growth Restriction; Maternal Exposure During Pregnancy	Prednisone			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17821134	EXPEDITED (15-DAY)		DE, HO, OT	US-ADVANZ PHARMA-202005005422			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Multiple Organ Dysfunction Syndrome; Off Label Use; Ventricular Arrhythmia; Ventricular Tachycardia	Hydroxychloroquine			S	Oral	400 Mg, Bid, Tablet		Concordia
	Hydroxychloroquine			S	Oral	200 Mg, Bid, Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17821167	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601682			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis	Actemra	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17821185	EXPEDITED (15-DAY)		HO	CA-ROCHE-2601280		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Ankylosing Spondylitis; Arthropathy; Condition Aggravated; Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Impaired	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

Gastric Emptying; Influenza; Off Label Use; Osteoarthritis; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Azathioprine	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Intramuscular	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Meloxicam	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17821230	EXPEDITED (15-DAY)		LT	CA-ROCHE-2598798		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity;	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Anakinra			S	Unknown			Not Reported

Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Anakinra	S		Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Cannabis Sativa	S	Unknown	Not Reported
	Cannabis Sativa	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S		Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S		Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Methotrexate	S		Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Oxycodone	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17821422	EXPEDITED (15-DAY)		HO	CA-ROCHE-2598993		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Ulcer	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Alendronate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Parenteral	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17821532	EXPEDITED (15-DAY)		OT	US-SLATE RUN PHARMACEUTICALS-20US000130			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Bradycardia; Cardiomyopathy; Electrocardiogram Qt Prolonged; Hypothermia; Torsade De Pointes; Ventricular Arrhythmia	Azithromycin Usp			S	Unknown			Hainan Poly Pharmaceutical
	Azithromycin Usp			S				Hainan Poly Pharmaceutical
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Not Reported
	Propofol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17821576	EXPEDITED (15-DAY)		OT	US-SLATE RUN PHARMACEUTICALS-20US000132			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Azithromycin Usp			S	Unknown	Unk		Hainan Poly Pharmaceutical
	Azithromycin Usp			S				Hainan Poly Pharmaceutical
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17821614	EXPEDITED (15-DAY)		HO, OT	FR-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-12-02		69 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Coronavirus Infection; Drug Ineffective; Hepatic Function Abnormal; Hypoxia;	Catapressan			S	Unknown	Unk		Boehringer Ingelheim
	Perfalgan			S	Unknown	1 G, Qid If Temprature Is Greater To 38.2		Not Reported
	Tazocilline			S	Unknown	Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			S	Subcutaneous	Unk Unk, Bid (8000 Ui)		Not Reported
	Bactrim			S	Unknown	Unk		Not Reported
	Inexium [Esomeprazole			S	Intravenous (not	40 Mg, Qd		Not Reported

Inflammation; Localised Oedema; Pneumonia; Pseudomonas Infection; Quarantine; Severe Acute Respiratory Syndrome; Spinal Disorder; Stenotrophomonas Infection	Magnesium]		otherwise specified)		
	Rocephine	S	Unknown	Unk	Not Reported
	Mucomyst [Acetylcysteine]	S	Unknown	1 Df, Qid (Sachet Sng)	Not Reported
	Dextro [Dextromethorphan Hydrobromide]	S	Unknown	Unk	Not Reported
	Claventin [Clavulanate Potassium;Ticarcillin Disodium]	S	Unknown	Unk	Not Reported
	Lederfoline	S	Unknown	Unk	Not Reported
	Tavanic	S	Unknown	500 Mg, Bid	Not Reported
	Eupressyl	S	Unknown	Unk	Not Reported
	Fortum [Ceftazidime]	S	Unknown	2 G, Tid	Not Reported
	Zithromax	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Tranxene	S	Unknown	2.5 Mg Pre Hour	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17821661	EXPEDITED (15-DAY)		OT	US-SLATE RUN PHARMACEUTICALS-20US000133			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Interval Abnormal	Azithromycin Usp			S	Unknown			Hainan Poly Pharmaceutical
	Azithromycin Usp			S				Hainan Poly Pharmaceutical
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17821771	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601274		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Off Label Use; Therapeutic Product Effect Decreased	Methotrexate	S	Oral		Not Reported
	Methotrexate	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Arava	C	Unknown		Not Reported
	Lyrica	C	Unknown		Not Reported
	Prednisone	C	Oral		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	11476817	EXPEDITED (15-DAY)		HO, OT	US-JAZZ-2014-US-010624			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Carbon Monoxide Poisoning; Carpal Tunnel Syndrome; Cyst Removal; Epilepsy; Infusion; Limb Operation; Loss Of Consciousness; Post Procedural Complication; Pruritus; Sciatica; Suicidal Ideation	Xyrem			S	Oral	1.75 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	3 G, Bid		Jazz
	Xyrem			S	Oral	3 G, Bid		Jazz
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	12370997	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016061225		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Off Label Use; Pneumonia; Prescribed Underdose; Rheumatoid Arthritis; Treatment Failure	Enbrel	S	Subcutaneous	Unk	Amgen
	Enbrel	S	Unknown	Unk	Amgen
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Prednisone	C		5 Milligram, Qd (Every 24 Hours)	Not Reported
	Prednisone	C	Unknown	10 Milligram, Bid	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	12842433	EXPEDITED (15-DAY)		OT	CA-ROCHE-1841433		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Knee Arthroplasty; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	1 Every 24 Hrs		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	13111752	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1876541			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Alopecia; Arthralgia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Condition Aggravated; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Musculoskeletal Disorder; Musculoskeletal Stiffness; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 12 Months		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported
	Humira			S	Subcutaneous	Solution For Injection In Pre-Filled Syringe		Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Ulcer	Methotrexate Sodium	S	Oral		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 9 Months	Not Reported
	Orencia	S	Unknown	Therapy Duration: 9 Months	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Unknown	Therapy Duration: 365 Nos Powder For Intravesical Solution	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Oral	Film-Coated Tablet	Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Myochrysine	S	Parenteral		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Myochrysine	S	Intramuscular		Not Reported

Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Alendronic Acid	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral	7300 Days	Not Reported
Hydroxychloroquine	S	Oral		Not Reported

	Apo-Hydroxyquine	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prednisone	C	Unknown	For 2 Months	Not Reported
	Prednisone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	13147472	EXPEDITED (15-DAY)		OT	CA-ROCHE-1840907			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral	8x 2.5 Mg Tablets		Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported

Arava	S	Oral			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Therapy Duration: 370.0 Day(S)		Not Reported
Hydroxychloroquine	S	Oral			Not Reported
Hydroxychloroquine	S	Oral			Not Reported
Folic Acid	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported
Simponi	C				Not Reported
Xeljanz	C	Oral			Not Reported
Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	14400613	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2017193304		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid	Enbrel			S	Subcutaneous	Unk		Amgen
	Etanercept			S	Unknown	Unk		Amgen
	Pantoloc [Pantoprazole]			S	Unknown	40 Milligram, Qd		Not Reported
	Pantoloc [Pantoprazole]			S	Unknown	40 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Oral	25 Milligram, Q2weeks		Not Reported
	Methotrexate Sodium			S	Oral	25 Milligram, 1/Week		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, 1/Week		Not Reported
	Methotrexate Sodium			S	Oral	25 Milligram, 1/Week		Not Reported
	Methotrexate Sodium			S	Oral	25 Milligram, Q2weeks		Not Reported
	Methotrexate Sodium			S	Oral	25 Milligram		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Q2weeks		Not Reported
	Methotrexate Sodium			S	Oral	Unk, Q2weeks		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Qd		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Bid		Not Reported

Arthritis	Sulfasalazine	S	Oral	1000 Milligram, Bid	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Bid	Not Reported
	Pantoprazole Sodium Anhydrous	S	Unknown	40 Milligram, 1x/Day	Not Reported
	Pantoprazole Sodium Sesquihydrate	S	Unknown	40 Milligram, 1x/Day	Not Reported
	Apo-Folic Acid	S	Unknown	5 Milligram, 2x/Week	Not Reported
	Apo-Folic Acid	S	Unknown	5 Milligram, 2x/Week	Not Reported
	Co Atenolol	S	Unknown	25 Milligram, Qd	Not Reported
	Co Atenolol	S	Unknown	20 Milligram, Qd	Not Reported
	Atenolol	S	Unknown	25 Milligram, Qd	Not Reported
	Naprosyn [Naproxen]	S	Oral	100 Milligram, Qd	Not Reported
	Naprosyn [Naproxen]	S	Oral	500 Milligram, Bid	Not Reported
	Naprosyn [Naproxen]	S	Oral	500 Milligram, 2x/Day	Not Reported
	Naprosyn [Naproxen]	S	Oral	1000 Milligram, 1x/Day	Not Reported
	Naproxen	S	Oral	100 Milligram, Qd	Not Reported
	Naproxen	S	Oral	500 Milligram, Qd	Not Reported
	Naproxen	S	Oral	500 Milligram, Qd	Not Reported
	Palafer Cf	S	Unknown	Unk, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	40 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
	Pantoprazole Teva	S	Unknown	40 Milligram, 1x/Day	Not Reported
	Pantoprazole Teva	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	20 Milligram, 1x/Day	Not Reported

Humira	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	Unk, Qd	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Adalimumab	S	Subcutaneous		Not Reported
Abatacept	S	Unknown	Unk	Not Reported
Ascorbic Acid	S	Unknown	Unk, 1x/Day	Not Reported
Ferrous Fumarate	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	5 Milligram, Bid	Not Reported
Folic Acid	S	Unknown	5 Milligram, 2 Times/Wk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, 2x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	40 Milligram, 1x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	40 Milligram, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	40 Milligram, Qd	Not Reported
Ferrous Fumarate;Folic Acid	S	Unknown	Unk, 1x/Day	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Naproxen Sodium	S	Unknown	500 Milligram, 2x/Day	Not Reported
Naproxen Sodium	S	Unknown	1000 Milligram, 1x/Day	Not Reported
Naproxen Sodium	S	Unknown	500 Milligram, 2x/Day	Not Reported
Naproxen Sodium	S	Unknown	100 Milligram, 2x/Day	Not Reported
Naproxen Sodium	S	Unknown	1000 Milligram, 1x/Day	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram, Weekly	Not Reported
Hydroxychloroquine	S	Unknown	40 Milligram, Weekly	Not Reported
Palafer	S	Unknown	Unk	Not Reported
Pantoprazole Sodium	S	Unknown	40 Milligram, 1x/Day	Not Reported
Celebrex	C	Oral	200 Milligram, Qd	Not Reported
Celebrex	C	Unknown	Unk	Not Reported

Celebrex	C	Oral	200 Milligram, Qd		Not Reported
Prednisone	C		5 Milligram, Qd		Not Reported
Celecoxib	C	Oral	Unk		Not Reported
Celecoxib	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	14692329	EXPEDITED (15-DAY)		OT	US-UCBSA-2018012947			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete; Tuberculosis	Cimzia			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Tofacitinib			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	15108403	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0760			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; No Adverse Event; Rheumatoid Arthritis; Treatment Failure	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Intramuscular			Not Reported
	Imuran			S				Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S				Not Reported

Plaquenil	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Etanercept	S		Not Reported
Apo-Hydroxyquine	S		Not Reported
Methotrexate Sodium	S		Not Reported
Apo-Hydroxyquine (Hydroxychloroquine Sulfate)	S		Not Reported
Rituxan (Rituximab)	S	Intravenous (not otherwise specified)	Not Reported
Remicade (Infliximab)	S	Intravenous (not otherwise specified)	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Orencia	S	Vaginal	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Wellbutrin	C		Not Reported
Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	15108415	EXPEDITED (15-DAY)		DS, OT	CA-BIOVITRUM-2018CA0742		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Event; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Deformity; Diarrhoea; Disease Progression; Drug Ineffective; Drug	Kineret			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Warfarin	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	15327973	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176030		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Sleep Disorder	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Minocycline	S	Unknown		Not Reported
Myochrysine	S	Parenteral		Not Reported
Myochrysine	S	Unknown		Not Reported
Myochrysine	S	Subcutaneous		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Otezla	S	Unknown		Not Reported
Otezla	S	Oral		Not Reported
Sirukumab	S	Unknown		Not Reported
Stelara	S	Subcutaneous		Not Reported
Stelara	S	Unknown		Not Reported
Xeljanz	S	Oral		Not Reported
Salazopyrin	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous		Not Reported
Minocin	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Orencia	C	Unknown	Therapy Duration: 4 Years	Not Reported
Methotrexate Sodium	C	Unknown		Not Reported
Methotrexate	C	Unknown		Not Reported
Methotrexate	C	Unknown		Not Reported
Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	15384496	EXPEDITED (15-DAY)		HO	CA-ROCHE-2181774		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported

Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Limb Deformity; Loose Body In Joint; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Naproxen	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	15415983	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186768			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; General Symptom; Neck Pain; Off Label Use; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

					otherwise specified)					
	Hydroxychloroquine Sulfate			S	Oral					Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous					Not Reported
	Mobicox			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	16079901	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-05867			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting; Wheelchair User	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Triamcinolone			S	Subcutaneous			Not Reported

	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Gamastan	S	Intravenous (not otherwise specified)	Liquid Intramuscular	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous, Dose- Unknown	Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Naproxen Sodium	S	Unknown	Unknown	Not Reported
	Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Unknown.	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Suspension Intra-Articular, Dose- Unknown	Not Reported
	Triamcinolone Acetonide	S			Not Reported
	Triamcinolone Hexacetonide	S	Intra-articular	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	16645866	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202728			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Plaquenil			S	Unknown			Sanofi
	Arava			S	Unknown			Sanofi
	Diclofenac Sodium			S	Unknown			Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Prednisone			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Actemra	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17090518	NON-EXPEDITED			US-UCBSA-2018026206			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Rash	Cimzia			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S		Injection		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17218475	EXPEDITED (15-DAY)		OT	GB-STRIDES ARCOLAB LIMITED-2019SP013302		23 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Behaviour Disorder; Confusional State; Headache; Infection; Liver Function Test Abnormal; Meningitis Enteroviral; Neck Pain; Off Label Use; Photophobia; Pyrexia;	Mycophenolate Mofetil			S	Unknown	Unk		Strides
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	150 Milligram		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	7.5 Milligram Per Day		Not Reported

Speech Disorder; Viral Upper Respiratory Tract Infection; Vomiting	Prednisolone	S	Oral	40 Milligram	Not Reported
	Prednisolone	S	Unknown	Weaned By 5 Mg Per Week To 5 Mg Daily	Not Reported
	Rituximab	S	Unknown	375 Mg/M2 In 2 Doses 14 Days Apart	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	1 G Infusion In 2 Doses 14 Days Apart	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17259819	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514963		22 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17337625	EXPEDITED (15-DAY)		OT	CA-ROCHE-2532612			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17465267	EXPEDITED (15-DAY)		OT	IT-ROCHE-2556901		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Pyrexia	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown	Unk Unk (7.5 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S	Unknown	Unk (50 Mg Qd, Tapering		Not Reported

				Dose)	
	Prednisone	S	Unknown	15 Mg, Qd	Not Reported
	Prednisone	S	Unknown	Unk Unk (15 Mg Qd, Dose Tapering)	Not Reported
	Prednisone	S	Unknown	Unk (25 Mg Qd, Dose Tapering)	Not Reported
	Prednisone	S	Unknown	Unk Unk (10 Mg Qd, Dose Tapering)	Not Reported
	Prednisone	S	Unknown	Unk Unk (12.5 Mg Qd, Dose Tapering)	Not Reported
	Envarsus	S	Unknown		Not Reported
	Belimumab	S	Unknown		Not Reported
	Belimumab	S	Unknown		Not Reported
	Belimumab	S	Unknown		Not Reported
	Rituximab	C	Unknown	Unk	Not Reported
	Methylprednisolone	C	Unknown	Unk (Pulses)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17559409	EXPEDITED (15-DAY)		DS	CA-ROCHE-2568722		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Drug Intolerance; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Indocid [Indometacin]			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Prednisone	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Cimzia	S	Unknown	Not Reported
	Gold (198 Au) Colloidal	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Cymbalta	C	Oral	Not Reported
	Folic Acid	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17694944	EXPEDITED (15-DAY)		OT	DE-BAUSCH-BL-2020-011287		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mycobacterium Marinum Infection	Prednisolone			S	Oral	Permanent 1-0-0		Not Reported
	Prednisolone			S	Oral	Intermittent Usage; Low-Dose; Two Weeks Before Presentation		Not Reported
	Prednisolone			S	Oral	Flare Medication 1-0-0		Not Reported
	Prednisolone			S	Oral	Flare Medication 1-0-0		Not Reported
	Prednisolone			S	Oral	Flare Medication 1-0-0		Not Reported
	Prednisolone			S	Oral	Flare Medication 1-0-0		Not Reported
	Prednisolone			S	Oral	Flare Medication 1-0-0		Not Reported

	Methotrexate	S	Subcutaneous		Not Reported
	Leflunomide	S	Oral	Intermittent Usage 1-0-0	Not Reported
	Sulfasalazine	S	Oral	2-0-2	Not Reported
	Hydroxychloroquine	S	Oral	1-0-1	Not Reported
	Metoprolol	C			Not Reported
	Amlodipine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17705408	EXPEDITED (15-DAY)		HO, OT	DE-PFIZER INC-2020165611		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Granuloma; Infective Tenosynovitis; Mycobacterium Marinum Infection	Methotrexate Sodium			S	Subcutaneous	15 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	2 Df, 2x/Day		Pfizer
	Prednisolone			S		Unk(Intermittent Usage Of Low-Dose Prednisolone)		Not Reported
	Prednisolone			S		20 Mg		Not Reported
	Leflunomide			S	Oral	10 Mg, 1x/Day		Not Reported
	Prednisone			S	Oral	40 Mg, 1x/Day		Not Reported
	Prednisone			S	Oral	30 Mg, 1x/Day		Not Reported
	Prednisone			S	Oral	20 Mg, 1x/Day(Two Weeks Before Presentation)		Not Reported
	Prednisone			S	Oral	20 Mg, 1x/Day		Not Reported
	Prednisone			S	Oral	15 Mg, 1x/Day		Not Reported
	Prednisone			S	Oral	10 Mg, 1x/Day		Not Reported
	Prednisone			S	Oral	7.5 Mg, 1x/Day		Not Reported
	Prednisone			S	Oral	5 Mg, 1x/Day		Not Reported
	Prednisone			S	Oral	4 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, 2x/Day		Not Reported
	Metoprolol			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17710023	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2020AP010277			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; C-Reactive Protein Increased; Condition Aggravated; Disability; Eye Disorder; Joint Swelling; Mobility Decreased; Musculoskeletal Pain; Ocular Toxicity; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Surgery; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown	20.0 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	400.0 Mg, Qd		Apotex
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50.0 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40.0 Mg, Q.O.Wk.		Not Reported
	Methotrexate			S	Oral	20.0 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	125.0 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17721825	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010320			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Drug Ineffective; Ocular Toxicity	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Methotrexate			S	Oral	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Prednisone			C	Unknown	20 Mg, Qd		Not Reported
	Sulfasalazine			C	Unknown	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17727113	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010387			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Gait Disturbance; Herpes Zoster; Musculoskeletal Pain; Musculoskeletal Stiffness; Rheumatoid Arthritis	Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Tramadol			C	Unknown	100 Mg, Qd		Not Reported
	Tramacet			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17733953	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010365			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17743772	EXPEDITED (15-DAY)		HO, OT	IT-VIIV HEALTHCARE LIMITED-IT2020073217		56 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Multiforme; Off Label Use; Oral Disorder; Rash Pruritic; Rash Pustular; Rash Vesicular; Stevens-Johnson Syndrome	Abacavirsulphate+Dolutegravir+ Lamivudine			S	Oral	1 Df, Qd		Viiv
	Symtuza			S	Oral	1 Df, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17746154	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010471		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alanine Aminotransferase Increased; Alopecia; Anxiety; Arthralgia; Aspartate Aminotransferase Increased; Asthenia; Depression; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis; Treatment Failure	Leflunomide			S	Unknown	20 Mg, Q.Wk.		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	9 Mg, Unk		Apotex
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Apo-Prednisone			S	Unknown	9 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Infliximab			S	Oral	5 Mg, Bid		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Q.Wk.		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	9 Mg, Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk, Q.M.T.		Not Reported

Xeljanz	S	Oral	5 Mg, Bid		Not Reported
Acetaminophen	C	Unknown	500 Mg, Unk		Not Reported
Cetirizine Hydrochloride	C	Unknown	10 Mg, Qd		Not Reported
Gabapentin	C	Unknown	600 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17749010	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590697		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Migraine; Mobility Decreased; Nausea; Off Label Use; Pain In Extremity; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 365.0		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 6.0 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 365.0		Not Reported
	Orencia			S	Unknown	Therapy Duration: 365.0		Not Reported
	Prednisone			S	Unknown			Not Reported

	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Pantoprazole	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17749983	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP010469		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Cellcept /01275102/			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	1 Ml, Q.Wk.		Not Reported
	Prednisone			C	Unknown	7 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17752335	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010525			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, Q.O.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Methotrexate			S	Unknown	20 Mg, Q.O.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Unk (Once In 6 Weeks)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Wellbutrin			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17764352	EXPEDITED (15-DAY)		OT	IT-ABBVIE-20K-083-3398690-00		62 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Off Label Use	Lopinavir/Ritonavir			S	Oral			Not Reported
	Roactemra			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Piperacillina/Tazobactam			C				Not Reported
	Inhixa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17765509	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS INC.-2020-02071		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Impaired Work Ability; Myopathy	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S				Lupin
	Chloroquine			S	Unknown	Unk		Not Reported
	Chloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17766041	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2020AP010461		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Injection Site Reaction; Intentional Product Use Issue; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet	Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	15 Mg, Q.O.Wk.		Not Reported
	Enbrel			S	Subcutaneous	15 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Intravenous (not otherwise specified)	15 Mg, Unk		Not Reported
	Etanercept			S	Subcutaneous	15 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	200 Mg, Q.M.T.		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	200 Mg, Q.Wk.		Not Reported

Count Increased; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Decreased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Methotrexate	S	Subcutaneous	15 Mg/M2, Q.Wk.		Not Reported
	Methotrexate	S	Subcutaneous	Unk Unk, Q.Wk.		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Orencia	S				Not Reported
	Plaquenil /00072602/	S	Unknown	Unk		Not Reported
	Rituximab	S	Unknown	Unk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	420 Mg, Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Tocilizumab	S	Unknown	Unk		Not Reported
	Tocilizumab	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17776898	EXPEDITED (15-DAY)		DE, OT	DE-ACCORD-181640		82 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure	Hydroxychloroquine			S	Oral	200 Mg 1-0-1		Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)	Strength: 500 Mg ,1-0-0		Not Reported
	Azithromycin			C				Not Reported
	Piperacillin Sodium/Tazobactam Sodium			C				Not Reported
	Tazobac			C				Not Reported
	Atorvastatin			C				Not Reported
	Meropenem			C				Not Reported
	Apixaban			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17787494	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1878868		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Arthritis; Therapeutic Product Effect Incomplete	Anakinra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Celecoxib	S	Unknown	Not Reported
	Celecoxib	S	Unknown	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported

Xeljanz	S	Oral	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Acetaminophen;Codeine Phosphate	C	Unknown	Not Reported
Altace	C	Unknown	Not Reported
Altace	C	Unknown	Not Reported
Apo-Gabapentin	C	Unknown	Not Reported
Apo-Gabapentin	C	Oral	Not Reported
Atorvastatin Calcium	C	Oral	Not Reported
Atorvastatin Calcium	C	Unknown	Not Reported
Cipralex [Escitalopram]	C	Unknown	Not Reported
Cipralex [Escitalopram]	C	Unknown	Not Reported
Conjugated Estrogens	C	Unknown	Not Reported
Conjugated Estrogens	C	Unknown	Not Reported
Cymbalta	C	Unknown	Not Reported
Cymbalta	C	Unknown	Not Reported
Cymbalta	C	Unknown	Not Reported
Escitalopram	C	Unknown	Not Reported
Gabapentin	C	Unknown	Not Reported
Gabapentin	C	Oral	Not Reported
Hydrochlorothiazide	C	Unknown	Not Reported
Hydromorphone Hydrochloride	C	Oral	Not Reported
Hydromorphone Hydrochloride	C	Oral	Not Reported
Mupirocin	C	Topical	Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Not Reported
Shark Liver Oil	C	Unknown	Not Reported
Tapentadol Hydrochloride	C	Unknown	Not Reported
Taro-Mupirocin	C	Topical	Not Reported

	Tramacet	C	Oral	Not Reported
	Tramadol Hydrochloride	C	Oral	Not Reported
	Citalopram Hydrobromide	C	Unknown	Not Reported
	Estrace	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17822140	EXPEDITED (15-DAY)		HO	CA-ROCHE-2602951		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17822233	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-025339		64 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Electrocardiogram Qt Prolonged	Amiodarone Arrow 200mg Scored Tablets			S	Oral	200 Milligram		Aurobindo
	Plaquenil			S	Oral	600 Milligram		Not Reported
	Zithromax			S	Oral	1 Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17822404	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2020-02333		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Exposure During Pregnancy; Foetal Death; Foetal Growth Restriction; Hypertension; Pre-Eclampsia; Thrombotic Microangiopathy; Weight Increased	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17822412	EXPEDITED (15-DAY)		OT	CH-TEVA-2020-CH-1239230		72 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral	800 Milligram Daily;		Teva
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Teva
	Atazanavir			S	Oral	400 Milligram Daily;		Not Reported
	Metoclopramide			S	Other	Route Of Administration : Intravenous And Oral		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)			Not Reported
	Cefepime			C	Intravenous (not otherwise specified)			Not Reported
	Rocuronium			C	Intravenous (not otherwise specified)			Not Reported
	Rocuronium			C	Intravenous (not otherwise specified)			Not Reported
	Midazolam			C	Intravenous (not otherwise specified)			Not Reported
	Propofol			C	Intravenous (not			Not Reported

		otherwise specified)		
Propofol	C	Intravenous (not otherwise specified)		Not Reported
Fentanyl	C	Intravenous (not otherwise specified)		Not Reported
Noradrenaline	C	Intravenous (not otherwise specified)		Not Reported
Furosemide	C	Intravenous (not otherwise specified)		Not Reported
Hydrochlorothiazide	C	Oral		Not Reported
Pravastatine	C	Oral	40 Milligram Daily;	Not Reported
Acetylsalicylic Acid	C	Other	100 Milligram Daily; Route Of Administration: Oral Or Intravenous	Not Reported
Metoprolol	C	Oral	50 Milligram Daily;	Not Reported
Torasemide	C	Oral		Not Reported
Ezetimibe	C	Oral	10 Milligram Daily;	Not Reported
Allopurinol	C	Oral	300 Milligram Daily;	Not Reported
Paracetamol	C	Oral	500 Milligram Daily;	Not Reported
Insuline	C			Not Reported
Clexane	C	Subcutaneous		Not Reported
Duphalac	C			Not Reported
Phosphore Phoscap	C	Oral		Not Reported
Supradyne Energy	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17822465	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-02402		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Gestational Diabetes; Gestational Hypertension; Nephritis;	Sulfamethoxazole And Trimethoprim			S	Unknown	Unk		Novel Labs
	Hydroxychloroquine			S	Unknown	Unk		Lupin

Treatment Noncompliance	Lovenox [Enoxaparin Sodium]	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk (Tapering Dose)	Not Reported
	Tacrolimus	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17822616	EXPEDITED (15-DAY)		OT	CA-SA-2020SA130913			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rash	Arava			S		Unk		Sanofi
	Methotrexate			S	Oral	1 Df, Qw		Not Reported
	Hydroxychloroquine Sulfate			S				Sanofi
	Sulfasalazine			S	Oral	1 G, Qow		Not Reported
	Prednisone			S		10 Mg, Qd		Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Mirtazapine			C		40 Mg, Qd		Not Reported
	Citalopram Hydrochloride			C		40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17822635	EXPEDITED (15-DAY)		OT	IT-ABBVIE-20K-083-3418091-00		58 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Kaletra			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Zitromax Avium			S	Oral	Zitromax Avium 600 Mg Compresse Rivest		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17822767	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-248011		83 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hyponatraemia	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram, Daily		Not Reported
	Symbicort Turbuhaler 160 Microgramos/4,5 Microgramos/Inhalacion Po...			S	Respiratory (inhalation)	2 Dosage Form, Tid		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Mg Dia		Not Reported
	Salbutamol			S	Respiratory (inhalation)	2-2-2 Inh		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17822816	EXPEDITED (15-DAY)		LT	FR-CADILA HEALTHCARE LIMITED-FR-ZYDUS-050341			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Azithromycin			S	Oral	250 Milligram, Qd		Zydus Pharm
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	400 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17822845	EXPEDITED (15-DAY)		OT	CA-SA-2020SA130998		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Arava			S	Unknown			Sanofi
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi

Minocycline Hydrochloride	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Azathioprine	S	Unknown	100 Mg		Not Reported
Enbrel	S	Unknown			Not Reported
Humira	S	Subcutaneous			Not Reported
Rituximab	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17822847	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131032			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Oral			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17822848	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131054			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pulmonary Toxicity	Arava			S	Unknown	20 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Sanofi
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported

	Actemra	S	Unknown	567 Mg, Qm	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Celebrex	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17822860	EXPEDITED (15-DAY)		OT	CA-ROCHE-1889961		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)	For 8 Months		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown	For 7 Months		Not Reported
	Humira			S	Subcutaneous	For 3 To 4 Months		Not Reported
	Leflunomide			S	Unknown	For 5 Months		Not Reported
	Methotrexate Sodium			S	Subcutaneous	For 7 Years		Not Reported
	Orencia			S	Unknown	For 7 Months		Not Reported
	Orencia			S	Subcutaneous	For 7 Months		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	For 4 Years		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Every 2 Weeks (For 6 Months)		Not Reported
	Xeljanz			S	Oral			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported

	Hydroxychloroquine	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Neoral	S	Oral	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Risedronate	C	Oral	Not Reported
	Arava	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17822874	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131144			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Arava			S	Unknown			Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi
	Methotrexate			S	Unknown	25.0 Mg		Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown	100.0 Mg		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Xeljanz			S	Unknown	5 Mg, Bid		Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17822875	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131129			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Fluid Retention; Joint Swelling; Memory Impairment; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Arava		S	Unknown	20 Mg	Sanofi
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Sanofi
	Methotrexate		S	Unknown	Unk	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Actemra		S	Unknown	Unk	Not Reported
	Xeljanz		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17822876	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131104		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug-Induced Liver Injury; Hepatitis	Leflunomide			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400.0 Mg		Sanofi
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17823051	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131299			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Nephrolithiasis; Somnolence; Visual Impairment	Arava			S	Oral	20 Mg, 1 Every 1 Day		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg 2 Every 2 Days		Sanofi
	Sulfasalazine			S	Oral	2000 Mg		Not Reported
	Paracetamol			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Methotrexate	C		25 Mg, Qw	Not Reported
	Meloxicam	C			Not Reported
	Hydromorphone Hydrochloride	C	Unknown		Not Reported
	Acetaminophen;Codeine Phosphate	C			Not Reported
	Celebrex	C	Oral	200 Mg, Qd	Not Reported
	Synthroid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17823052	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA131308			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Arava			S	Unknown	20 Mg		Sanofi
	Boric Acid			S	Unknown	Unk		Not Reported
	Benzalkonium Chloride			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Sanofi
	Methotrexate			S	Oral	15 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Phenylephrine Hydrochloride			S	Unknown	Unk		Sanofi
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg, Qd		Not Reported
	Benzalkonium Chloride;Diphenhydramine Hydrochloride;Phenylephrine Hydr			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported

Disodium Edetate	S	Unknown	Unk		Not Reported
Enbrel	S	Subcutaneous	40 Mg, Qw		Not Reported
Gold	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	40 Mg		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Unknown	Unk		Not Reported
Simponi	S	Unknown	Unk		Not Reported
Sodium Borate	S	Unknown	Unk		Not Reported
Tofacitinib Citrate	S	Unknown	10 Mg, Biw		Not Reported
Tofacitinib Citrate	S	Unknown	5 Mg, Biw		Not Reported
Tofacitinib Citrate	S	Subcutaneous	5 Mg, Biw		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported
Ibuprofen	C	Oral	400 Mg		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Celebrex	C	Oral	400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17823059	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131297			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Pneumocystis Jirovecii Pneumonia; Pulmonary Fibrosis; Synovitis	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17823101	EXPEDITED (15-DAY)		HO	CA-ROCHE-2599694		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hepatic Enzyme Increased; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)	126.0 Days		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	17.0 Days		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Gold			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Leflunomide			C				Not Reported
	Lyrica			C				Not Reported
	Prednisone			C				Not Reported
	Tocilizumab			C	Unknown			Not Reported
	Trazodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17823135	EXPEDITED (15-DAY)		OT	NVSC2020US142630			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Methylprednisolone			S	Transplacental	Unk (Mother Dose 1 G And 1 Mg/Kg)		Novartis
	Amoxicillin			S	Transplacental	Unk (Mother Dose: 500 Mg Daily)		Not Reported
	Azithromycin			S	Transplacental	Unk (Mother Dose: 500 Mg Daily)		Not Reported

Vancomycin	S	Transplacental	Unk (Mother Dose: 750 Mg, Q8h And 1250 Mg, Q8h)		Not Reported
Fluconazole	S	Transplacental	Unk		Not Reported
Hydroxychloroquine	S	Transplacental	Unk (Mother Dose: 200 Mg Bid)		Not Reported
Prednisone	S	Transplacental	Unk (Mother Doses: 70 Mg Qd, 60 Mg Qd, 50 Mg Qd, 40 Mg Qd)		Not Reported
Cefepime	S	Transplacental	Unk (Mother Dose: 2g Q8h)		Not Reported
Acyclovir	S	Transplacental	Unk (Mother Dose: 800 Mg Qd)		Not Reported
Acyclovir	S	Transplacental	Unk (Mother Dose: 5 Mg/Kg, Q8h)		Not Reported
Cyclophosphamide	S	Transplacental	Unk (Mother Dose: 500 Mg And 840 Mg)		Not Reported
Magnesium Sulfate	S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17823242	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1051022		25 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pruritus; Rash	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	200 Milligram, Qd		Mylan
	Augmentin /00852501/			S	Oral	1 Gram, Qd		Mylan
	Clexane			C	Subcutaneous	1 Dosage Form, Qd		Mylan
	Dicloreum /00372301/			C	Intramuscular	1 Dosage Form, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17823332	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-247053			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia Neonatal; Bronchopulmonary Dysplasia; Failure To Thrive; Foetal Exposure During Pregnancy; Infantile Apnoea; Low Birth Weight Baby; Postnatal Growth Restriction; Premature Baby; Pulmonary Hypertension; Retinopathy Of Prematurity	Prednisone			S	Unknown	Unk		Sun
	Aspirin			S	Unknown	Unk		Sun
	Insulin			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17823333	EXPEDITED (15-DAY)		HO	CA-ROCHE-2603909			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Asthenia; Astigmatism; Balance Disorder; Blood Glucose Increased; Cataract; Dizziness; Fall; Fatigue; Feeling Hot; Gastric Disorder; Gastrointestinal Disorder; Head Discomfort; Headache; Hot Flush; Hypersomnia; Incorrect Dose Administered; Insomnia; Irritable Bowel Syndrome; Kidney Infection; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Pain; Nasal Congestion; Nausea; Neck Pain; Nephrolithiasis;	Mycophenolate Mofetil			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Neurontin			C	Oral			Not Reported
	Gravol			C	Unknown			Not Reported

Oropharyngeal Discomfort; Pain; Pain In Extremity; Pruritus; Raynaud'S Phenomenon; Sepsis; Sinusitis; Sleep Apnoea Syndrome; Stress; Therapeutic Product Effect Decreased; Toxicity To Various Agents; Upper Respiratory Tract Congestion; Urinary Tract Infection; Vision Blurred; Visual Acuity Reduced; Visual Impairment; Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17823551	NON-EXPEDITED			US-PFIZER INC-2020203536		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Peripheral Swelling	Xeljanz Xr			S		11 Mg		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17823651	NON-EXPEDITED			US-MYLANLABS-2020M1046393			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Dizziness; Dyspnoea; Feeling Abnormal; Malaise; Product Packaging Issue; Sensation Of Foreign Body	Hydroxychloroquine Sulfate Tablets, Usp			S	Oral	Unk		Mylan
	Hydroxychloroquine Sulfate Tablets, Usp			S				Mylan
	Carvedilol Tablets, Usp			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17823953	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-17351			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Immune Globulin (Human)			S	Unknown	Unknown		Not Reported
	Immune Globulin (Human)			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown	Unknown		Not Reported

	Triamcinolone Hexacetonide	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824015	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-247852		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Sun
	Prednisone			S	Unknown	Unk		Mutual

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824306	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602237		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Cataract; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Eye Disorder; Glaucoma; Hernia; Herpes Zoster; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Off Label Use; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Glumetza			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Acetaminophen	C	Unknown	Not Reported
Altace	C	Unknown	Not Reported
Arava	C	Unknown	Not Reported
Asa	C	Unknown	Not Reported
Codeine	C	Unknown	Not Reported
D-Alpha Tocopherol	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Prednisone	C	Oral	Not Reported
Rosuvastatin Calcium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824335	EXPEDITED (15-DAY)		HO, OT	LV-PFIZER INC-2020205931		12 YR	Female	LVA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Pneumonitis; Systemic Lupus Erythematosus; Weight Decreased	Methylprednisolone			S	Unknown	4 Mg, 1x/Day		Pfizer
	Roactemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824360	EXPEDITED (15-DAY)		DE, OT	DE-PFIZER INC-2020206049		82 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, 2x/Day		Not Reported

	Tazobac	C	Not Reported
	Tazobac	C	Not Reported
	Atorvastatin	C	Not Reported
	Meropenem	C	Not Reported
	Apixaban	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824544	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2598810		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown	9999		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Cortisone			S	Oral			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac			S	Unknown			Not Reported

Diclofenac Sodium	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Fosamax	S	Unknown	Not Reported
Fosamax	S	Oral	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Subcutaneous	Not Reported
Phthalylsulfathiazole	S	Oral	Not Reported
Phthalylsulfathiazole	S	Oral	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Prednisone	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Tofacitinib	S	Unknown	Not Reported

	Tofacitinib Citrate	S	Unknown	Not Reported
	Topicorten	S	Cutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824615	EXPEDITED (15-DAY)		HO	CA-ROCHE-2600446		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Contraindicated Product Administered; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hepatic Enzyme Increased; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Apo-Gabapentin			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Nortriptyline			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown	Tablet (Extended-Release)		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Acetaminophen			C				Not Reported
	Acetaminophen;Oxycodone Hydrochloride			C				Not Reported

Aclasta	C	Intravenous (not otherwise specified)	Not Reported
Actonel	C	Unknown	Not Reported
Cholecalciferol	C		Not Reported
D-Alpha Tocopheryl Acetate	C	Unknown	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Esomeprazole	C	Unknown	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
Ferrous Gluconate	C	Unknown	Not Reported
Lomotil [Loperamide Hydrochloride]	C	Unknown	Not Reported
Loperamide	C		Not Reported
Loperamide Hydrochloride	C	Unknown	Not Reported
Nasonex	C	Unknown	Not Reported
Oxycodone Terephthalate	C		Not Reported
Pantoprazole Magnesium	C	Unknown	Not Reported
Perphenazine	C		Not Reported
Prednisone	C	Unknown	Not Reported
Trazodone	C	Unknown	Not Reported
Trazodone Hydrochloride	C	Unknown	Not Reported
Tylenol	C	Unknown	Not Reported
Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824666	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131015			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Leflunomide			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported

	Actemra	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824667	EXPEDITED (15-DAY)		OT	CA-SA-2020SA130990			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Mobility Decreased; Osteomyelitis; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, 1 Every 1 Day		Sanofi
	Methotrexate			S	Unknown	20 Mg		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, 4 Every 1 Day		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Acetaminophen			C	Unknown	500 Mg		Not Reported
	Hydrocortisone Valerate			C	Unknown	Unk		Not Reported
	Hydromorphone Hydrochloride			C	Unknown	Unk		Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported
	Lyderm [Fluocinonide]			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	250 Mg, Qd		Not Reported
	Prednisone			C	Unknown	10 Mg, Qd		Not Reported
	Sodium Aurothiomalate			C	Unknown	Unk Unk, Qcy		Not Reported
	Sodium Aurothiomalate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824794	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598916		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Drug Ineffective; Hypersensitivity; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S				Not Reported
	Fosamax			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Diclofenac	C	Unknown	Not Reported
Salazopyrin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824860	DIRECT					48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Impaired Work Ability; Insomnia; Pain;	Hydroxychloroquine Sulfate - Plauenil	Y		S		Quantity:1 Tablet(S);		Zydus Pharm
Product Quality Issue;	Eliquis			C				Not Reported
Product Substitution Issue;	Lasix			C				Not Reported
Therapeutic Product Effect Incomplete	Telenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17825304	NON-EXPEDITED			US-UCBSA-2019010565			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Blood Glucose	Cimzia			S				Not Reported

Increased; Eye Disorder; Migraine; Nausea; Treatment Failure	Humira		S	Subcutaneous	Unk	Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Orencia		S			Not Reported
	Simponi		S			Not Reported
	Methotrexate		S	Oral	Unk	Not Reported
	Methotrexate		S		Unk	Not Reported
	Leflunomide		S		Unk	Not Reported
	Hydroxychloroquine		S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17825441	EXPEDITED (15-DAY)		HO	CA-ROCHE-2600041		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Asthenia; Condition Aggravated; Contraindicated Product Administered; Cough; Drug Ineffective; Fatigue; Fine Motor Skill Dysfunction; Goitre; Headache; Inflammation; Joint Swelling; Lower Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Thyroid Disorder	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral	Therapy Duration: 21.0 Years		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Simponi	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Rosuvastatin Calcium	C		Not Reported
	Citalopram Hydrobromide	C		Not Reported
	Ketoprofen	C	Unknown	Not Reported
	Losec [Omeprazole]	C	Unknown	Not Reported
	Naprosyn [Naproxen]	C	Unknown	Not Reported
	Omeprazole	C		Not Reported
	Prednisone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17825445	EXPEDITED (15-DAY)		DS	CA-ROCHE-2599544		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Injection Site Reaction; Intentional Product Use Issue; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased;	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Therapy Duration: 1.0 Months		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S				Not Reported
	Adalimumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 610.0 Days		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported

Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Decreased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Humira		S	Subcutaneous	Therapy Duration: 4.0 Years	Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Infliximab		S	Intravenous (not otherwise specified)	Therapy Duration: 2.0 Months	Not Reported
	Infliximab		S	Intravenous (not otherwise specified)		Not Reported
	Leflunomide		S	Oral	Therapy Duration: 2.0 Months	Not Reported
	Methotrexate		S	Subcutaneous	Therapy Duration: 2.0 Months	Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Orencia		S	Unknown		Not Reported
	Orencia		S			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17825474	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020205625		58 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Repolarisation Abnormality; Hepatocellular Injury; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	2 Df, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	2 Df, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17825475	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020205699		34 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use; Product Use In Unapproved Indication; Tachycardia	Zithromax		S	Oral	250 Mg, 1x/Day	Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	600 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17825739	EXPEDITED (15-DAY)		DE, OT	ES-TEVA-2020-ES-1239023		90 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily; 400 Mg		Teva
	Morfina (1982a)			S	Intravenous (not otherwise specified)	Sedation		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr		Not Reported
	Furosemida			C	Oral	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17825755	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236224			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Prednisone			S	Unknown			Actavis
	Adalimumab			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil[Hydroxychloroquinesulfate]	S	Unknown	400 Ml Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tofacitinib Citrate	S	Unknown		Not Reported
	Hydroxychloroquine Phosphate	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17826171	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1240209		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cornea Verticillata	Hydroxychloroquine			S	Unknown	1200 Milligram Daily;		Teva
	Hydroxychloroquine			S	Unknown	1200 Milligram Daily; 21.9 Mg/Kg/Day		Teva
	Everolimus			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17826300	EXPEDITED (15-DAY)		OT	IT-ADVANZ PHARMA-202005005429			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Injury; Off Label Use; Syncope	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

Azithromycine	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17826306	EXPEDITED (15-DAY)		OT	IT-ADVANZ PHARMA-202005005461			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Off Label Use; Total Lung Capacity Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17826307	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202005005455			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Discomfort; Condition Aggravated; Drug Ineffective; Gastrointestinal Disorder; Malaise; Off Label Use; Product Use Issue; Skin Lesion; Swelling; Treatment Failure	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Leflunomide			S	Unknown	Film-Coated Tablet		Not Reported
	Methotrexate			S	Oral	20 Mg, Q2m		Not Reported
	Prednisone			S	Unknown			Not Reported
	Folic Acid			C		Unk		Not Reported
	Fish Oil			C		Unk		Not Reported
	Vitamin D 2000			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17826310	EXPEDITED (15-DAY)		DE, HO, OT	US-ADVANZ PHARMA-202005005511			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Multiple Organ Dysfunction Syndrome; Off Label Use; Ventricular Arrhythmia; Ventricular Tachycardia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Bid For 1 Day		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Bid For 4 Days		Concordia
	Azithromycin			S	Unknown	500 Mg, Qd For 5 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17826524	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20200523250		77 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticoagulation Drug Level Increased; Drug Interaction	Rivaroxaban			S	Oral	15 Mg, Qd		Janssen
	Lopinavir			S	Unknown	Unk		Not Reported
	Ritonavir			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17826528	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20200523246		82 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anticoagulation Drug Level Increased; Drug Interaction	Rivaroxaban			S	Oral	15 Mg, Qd		Janssen
	Lopinavir			S				Not Reported
	Ritonavir			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17826917	EXPEDITED (15-DAY)		OT	NVSC2020GB139840			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dactylitis; Drug Ineffective; Dry Skin; Emphysema; Hypoaesthesia; Joint Injury; Joint Swelling; Joint Swelling; Nausea; Paraesthesia; Psoriatic Arthropathy; Rash; Rheumatoid Nodule; Therapeutic Product Effect Incomplete	Cosentyx			S	Oral	300 Mg		Novartis
	Cosentyx			S	Oral	40 Mg		Novartis
	Methotrexate			S	Oral	10 Mg, (10 Mg To 15 Mg)		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Methotrexate			S	Oral	30 Mg		Not Reported
	Methotrexate			S	Oral	15 Mg		Not Reported

Sulfasalazine	S	Unknown	2 G, Qd		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	2 G, Qd		Not Reported
Sulfasalazine	S	Unknown	4 G, Qd		Not Reported
Sulfasalazine	S	Unknown	3 G, Qd		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Unknown	400 Mg		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Humira	S	Subcutaneous	1 Ot, Tiw		Not Reported
Humira	S	Subcutaneous	1 Unk, Q4w		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Leflunomide	C	Unknown	20 Mg		Not Reported
Leflunomide	C	Unknown	10 Mg,		Not Reported
Leflunomide	C	Unknown	20 Mg,		Not Reported
Tocilizumab	C	Subcutaneous	162 Mg, Qw		Not Reported
Abatacept	C	Subcutaneous	125 Mg,		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17826954	EXPEDITED (15-DAY)		OT	NVSC2020CA034842		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; C-Reactive Protein Increased; Decreased Appetite; Drug Ineffective; Dysstasia; Fatigue; Gait Disturbance; General Physical Health Deterioration; Grip Strength Decreased; Hypokalaemia; Nausea; Pain	Methotrexate			S	Unknown	Unk		Novartis
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Plaquenil			C	Unknown	Unk		Not Reported
	Ibuprofen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	10700712	EXPEDITED (15-DAY)		DS	FR-ELI_LILLY_AND_COMPANY-FR201412010311		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Peripheral Sensorimotor Neuropathy	Cymbalta			S	Oral	Unk, Unknown		Eli Lilly And Co
	Plaquenil /00072602/			S	Oral	Unk, Unknown		Not Reported
	Salazopyrine			S	Oral	Unk, Unknown		Not Reported
	Tahor			S	Oral	Unk, Unknown		Not Reported
	Metoject			S	Subcutaneous	Unk, Unknown		Not Reported
	Skenan			S	Oral	Unk, Unknown		Not Reported
	Cortancyl			S	Oral	Unk, Unknown		Not Reported
	Inexium /01479302/			S	Oral	Unk, Unknown		Not Reported
	Fosamax			S	Oral	Unk, Unknown		Not Reported
	Avodart			S	Oral	Unk, Unknown		Not Reported
	Cacit Vitamine D3			S	Oral	Unk, Unknown		Not Reported
	Rivotril			S	Oral	Unk, Unknown		Not Reported
	Lexomil			S	Oral	Unk, Unknown		Not Reported
	Forlax /00754501/			S	Oral	Unk, Unknown		Not Reported
	Lasilix /00032601/			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	11567356	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-1638076		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C-	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 153 Days		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 6.0 Months		Not Reported
	Actemra			S	Intravenous (not			Not Reported

Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Actemra	S	otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Naproxen	S	Intravenous (not otherwise specified)		Not Reported
	Naproxen	S	Unknown		Not Reported
	Naproxen	S	Unknown		Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Oral	Therapy Duration: 10 Years	Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 63 Days, Therapy Duration: 3 Months	Not Reported
	Orencia	S	Respiratory (inhalation)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Qmo	Not Reported
	Humira	S	Subcutaneous	Therapy Duration: 3 Months Therapy Duration: 62 Days	Not Reported
	Kineret	S	Subcutaneous	Therapy Duration: 700 Days, Therapy Duration: 3 Years	Not Reported

Kineret	S	Subcutaneous		Not Reported
Kineret	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous	Therapy Duration: 8.0 Month(S)	Not Reported
Enbrel	S	Subcutaneous	Therapy Duration: 4 Months	Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Cyclical	Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Therapy Duration: 5 Months	Not Reported
Infliximab	S	Unknown	Therapy Duration: 62 Days	Not Reported
Sulfasalazine	S	Oral	500 Mg Tablet	Not Reported
Triamcinolone	S	Subcutaneous		Not Reported
Triamcinolone	S	Unknown		Not Reported
Triamcinolone	S	Subcutaneous		Not Reported
Iviglob-Ex	S	Intravenous (not otherwise specified)	Therapy Duration: 3 Months	Not Reported
Iviglob-Ex	S	Intravenous (not otherwise specified)	Therapy Duration: 3 Months	Not Reported
Iviglob-Ex	S	Unknown		Not Reported
Iviglob-Ex	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported

Abatacept	S	Intravenous (not otherwise specified)		Not Reported
Abatacept	S	Intravenous drip	Therapy Duration: 3 Months	Not Reported
Anakinra	S	Subcutaneous	Therapy Duration: 3 Years	Not Reported
Anakinra	S	Unknown		Not Reported
Anakinra	S	Subcutaneous	Therapy Duration: 3 Years	Not Reported
Apo-Hydroxyquine	S	Oral		Not Reported
Triamcinolone Acetonide	S	Intra-articular	Suspension Intra-Articular	Not Reported
Etanercept	S	Subcutaneous		Not Reported
Etanercept	S	Subcutaneous	Cyclic Therapy Duration: 4 Months	Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Adalimumab	S	Subcutaneous		Not Reported
Adalimumab	S			Not Reported
Gammagard	S	Intravenous (not otherwise specified)	Therapy Duration: 3 Months	Not Reported
Apo-Naproxen	S	Unknown		Not Reported
Apo-Naproxen	S	Oral		Not Reported
Apo-Naproxen	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Triamcinolone Hexacetonide	S	Unknown		Not Reported
Gamastan	S	Intramuscular		Not Reported
Folic Acid	C			Not Reported
Triamcinolone Hexacetonide	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	13059019	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-APOTEX-2016AP015792		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Apparent Death; Arthropathy; C-	Apo-Leflunomide			S	Unknown	Unk		Apotex

Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Apo-Leflunomide	S	Oral	Unk	Apotex
	Leflunomide	S	Unknown	Unk	Apotex
	Leflunomide	S	Oral	Unk	Apotex
	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Hydroxychloroquine	S	Oral	Unk	Apotex
	Hydroxychloroquine	S			Apotex
	Minocycline	S	Unknown	Unk	Not Reported
	Oxycodone	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S			Not Reported
	Sulfasalazine	S			Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S			Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Ilaris	S	Unknown	Unk	Not Reported
	Ilaris	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Ilaris	S			Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S			Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S			Not Reported

Plaquenil /00072602/	S	Unknown		Not Reported
Plaquenil /00072602/	S			Not Reported
Remicade	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Arava	S			Not Reported
Arava	S			Not Reported
Xeljanz	S	Oral	Unk, Bid	Not Reported
Xeljanz	S	Unknown	5 Mg, Q.O.Wk.	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Marijuana	S	Unknown	Unk	Not Reported
Cannabis Sativa	S	Unknown	Unk	Not Reported
Kineret	C	Unknown	Unk	Not Reported
Lyrica	C	Oral	Unk	Not Reported
Plaquenil /00072602/	C	Oral	Unk	Not Reported
Prednisone	C	Unknown	Unk Unk, Qd	Not Reported
Rituximab W/Urelumab	C	Unknown	Unk	Not Reported
Urelumab	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	13121306	EXPEDITED (15-DAY)		OT	CA-SA-2017SA006034		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Affect Lability; Anxiety; Blood Pressure Fluctuation; Depression; Drug Ineffective; Finger Deformity; Foot Operation; Headache; Hyperhidrosis; Joint Swelling; Nausea; Night Sweats; Osteoarthritis; Palpitations; Rheumatoid Arthritis; Therapeutic Response Decreased	Plaquenil	S	Unknown	Unk Unk,Unk	Sanofi
	Arava	S	Oral	20 Mg,Qd	Sanofi
	Enbrel	S	Subcutaneous	50 Mg,Qw	Not Reported
	Sulfasalazine	S	Oral	Unk Unk,Unk	Not Reported
	Cimzia	S	Unknown	200 Mg,Qow	Not Reported
	Humira	S	Unknown	40 Mg,Qow	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Mg,Unk	Not Reported
	Methotrexate Sodium	S	Oral	25 Mg,Qw	Not Reported
	Methotrexate Sodium	S	Oral	17.5 Mg,Qw	Not Reported
	Methotrexate Sodium	S	Oral	15 Mg,Qw	Not Reported
	Folinic Acid	C	Unknown	Unk Unk,Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk Unk,Unk	Not Reported
	Perindopril	C	Unknown	Unk Unk,Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk Unk,Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	14223391	EXPEDITED (15-DAY)		HO, LT, OT	CA-APOTEX-2017AP021500		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Unk, Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 G, Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S				Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Minocycline			S	Unknown	Unk		Not Reported
	Oxycodone			S	Unknown	10 Mg, Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported

Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S			Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S			Not Reported
	Cannabis Sativa	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Ilaris	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S			Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Lyrica	C	Unknown	Unk	Not Reported
	Marijuana	C	Unknown	Unk	Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Unk	Not Reported

Oxycodone	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	7 Mg, Qd		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Mg, Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Anakinra	C	Unknown	Unk		Not Reported
Rituximab W/Urelumab	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	14535482	EXPEDITED (15-DAY)		DS, OT	CA-BIOVITRUM-2018CA0123			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Arthralgia; Arthropathy; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug Ineffective; Foot Deformity; Foot Operation; Hepatotoxicity; Ill-Defined Disorder; Infection; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Nausea; Neck Pain; Nodule; Off Label Use; Pain; Rheumatoid Arthritis; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Kineret			S	Subcutaneous			Not Reported
	Kineret			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
Simponi	S	Subcutaneous		Not Reported
Gold	S			Not Reported
Plaquenil	S			Not Reported
Plaquenil	S	Oral		Not Reported
Apo-Hydroxyquine	S			Not Reported
Methotrexate	S		Dose: 17.5 Mg	Not Reported
Methotrexate	S			Not Reported
Actonel	S			Not Reported
Apo-Leflunomide	S			Not Reported
Certolizumab Pegol	S	Subcutaneous		Not Reported
Codeine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Prednisone	C	Intravenous (not otherwise specified)		Not Reported
Adalimumab	C	Unknown		Not Reported
Adalimumab	C			Not Reported
Xeljanz	C	Unknown		Not Reported
Methotrexate	C		Dosage Form: Not Specified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	14535486	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-BIOVITRUM-2018CA0124		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Product Use In Unapproved Indication; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Anakinra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S		Not Reported
	Apo Sulfasalazine Tab 500mg	S		Not Reported
	Apo Sulfasalazine Tab 500mg	S		Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S		Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S		Not Reported

Methotrexate	S	Intra-arterial	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate Sodium	S		Not Reported
Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
Ilaris Single-Use Vial	S	Unknown	Not Reported
Ilaris Single-Use Vial	S	Intravenous (not otherwise specified)	Not Reported
Gold	S	Unknown	Not Reported
Gold	S		Not Reported
Leflunomide	S	Oral	Not Reported
Leflunomide	S		Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S		Not Reported
Arava	S	Unknown	Not Reported
Arava	S		Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Sodium Aurothiomalate	S		Not Reported
Cannabis Sativa	S		Not Reported
Cannabis Sativa	S		Not Reported
Oxycodone	S		Not Reported
Minocycline Hydrochloride	S		Not Reported
Rituximab	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Minocycline	S	Unknown	Not Reported
Oxyquinoline Sulfate	S		Not Reported

Xeljanz	S	Oral		Not Reported
Sulfasalazine	S		Coated Tablet	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S			Not Reported
Hydroxychloroquine Sulfate	S			Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Marijuana	S			Not Reported
Lyrica	C			Not Reported
Urelumab	C	Unknown		Not Reported
Kineret	C			Not Reported
Lyrica	C	Oral		Not Reported
Plaquenil	C			Not Reported
Prednisone	C	Unknown		Not Reported
Rituximab	C			Not Reported
Xeljanz	C	Oral		Not Reported
Xeljanz	C			Not Reported
Xeljanz	C	Oral		Not Reported
Xeljanz	C	Unknown		Not Reported
Kineret	C			Not Reported
Lyrica	C	Oral		Not Reported
Plaquenil	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	15428288	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189244		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis;	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported

Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	15543164	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016253265		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Off Label Use; Pneumonia; Prescribed Underdose; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Unknown
	Enbrel			S	Unknown	Unk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk (Powder And Solvent For Solution For Injection/Infusion)		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

			otherwise specified)		
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Not Reported
	Prednisone	C	Unknown	5 Mg, 1x/Day (Every 24 Hours)	Not Reported
	Prednisone	C	Unknown	10 Mg, 2x/Day	Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	15834762	EXPEDITED (15-DAY)		OT	CA-ROCHE-2245786		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	15932350	EXPEDITED (15-DAY)		HO, OT	US-SA-2019SA030298		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Atrioventricular Block; Coronary Artery Occlusion; Herpes Zoster; Mobility Decreased; Osteoporosis; Spinal Fracture	Ambien			S	Unknown	Unk Unk, Unk		Sanofi
	Nifedipine			S	Unknown	Unk, Unk		Not Reported
	Metoclopramide Hydrochloride			S	Unknown	Unk, Unk		Not Reported
	Trazodone Hydrochloride			S		Unk, Unk		Not Reported
	Loperamide			S	Unknown	Unk, Unk		Not Reported
	Gabapentin			S	Unknown	Unk, Unk		Not Reported
	Esomeprazole Magnesium			S	Unknown	Unk, Unk		Not Reported
	Isosorbide Mononitrate			S				Not Reported
	Plavix			S	Unknown			Sanofi
	Famotidine			S				Not Reported
	Rosuvastatin Calcium			S				Not Reported
	Potassium			S				Not Reported
	Glyceryl Trinitrate			S				Sanofi
	Venlafaxine Hydrochloride			S	Unknown			Not Reported
	Doxycycline			S				Not Reported
	Trandolapril			S				Not Reported
	Prednisone			S				Not Reported
	Hydroxychloroquine			S				Sanofi
	Flomax			S				Sanofi
	Furosemide			S				Sanofi
	Victoza			S				Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Humira			S	Subcutaneous	40 Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	16691241	EXPEDITED (15-DAY)		OT	CA-SA-2019SA208333		50 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Breast Cancer Stage Iii; Depression; Diarrhoea; Sleep Disorder; Treatment Noncompliance	Arava	S		Unk	Sanofi
	Hydroxychloroquine	S		Unk	Sanofi
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S		Unk	Not Reported
	Enbrel	S		Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S		Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	16720233	EXPEDITED (15-DAY)		OT	CA-SA-2019SA217087		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Depression; Drug Ineffective; Finger Deformity; Foot Operation; Headache; Hyperhidrosis; Joint Swelling; Nausea; Night Sweats; Osteoarthritis; Palpitations; Rheumatoid Arthritis; Therapeutic Response Decreased	Arava			S	Oral	20 Mg, Qd		Sanofi
	Plaquenil			S	Unknown	Unk		Sanofi
	Sulfasalazine			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Methotrexate			S	Oral	17.5 Mg, Qw		Not Reported
	Methotrexate			S	Oral	15 Mg, Qw		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Qow		Not Reported
	Leucovorin [Calcium Folinate]			C	Unknown	Unk		Not Reported
	Ergocalciferol			C		Unk		Not Reported
	Coversyl [Perindopril Arginine]			C	Unknown	Unk		Not Reported
	Vitamin D [Ergocalciferol]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	16774890	EXPEDITED (15-DAY)		OT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-219753			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Oedema Peripheral; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Ramipril			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Ranbaxy
	Ramipril			S	Unknown	5 Milligram		Ranbaxy
	Pregabalin			S	Unknown	100 Milligram, Tid		Sun
	Omeprazole			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Astrazeneca
	Omeprazole			S	Unknown	20 Mg, Bid		Astrazeneca
	Volibris			S	Oral	30 Milligram, Qd		Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qw		Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qw		Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1 - 0 - 1)		Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1 - 0 - 1)		Not Reported
	Quensyl			S	Unknown	20 Mg Bid		Not Reported
	Eliquis			S	Unknown	2.5 Milligram, Bid		Not Reported
	Spasmolyt			S	Unknown	1 Df, Qd		Not Reported
	Spasmolyt			S	Unknown	30 Mg, Qd		Not Reported
	Spasmolyt			S	Unknown	15 Milligram		Not Reported
	Spasmolyt			S	Unknown			Not Reported
	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported
	Ambrisentan			S	Unknown	1 Dosage Form, Qd		Not Reported
	Lyrica			S	Unknown	300 Milligram, Daily		Not Reported

	Lyrica		S		1 Df, Tid (1 Df, 3x/Day (1 - 1- 1))	Not Reported
	Eliquis		S	Unknown	2 Dosage Form, Daily	Not Reported
	Apixaban		S	Unknown	2 Df, Qd	Not Reported
	Apixaban		S	Unknown	2.5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	16884537	EXPEDITED (15-DAY)		OT	CA-ROCHE-2418235		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S	Endocervical			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Ciclosporin			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17081625	NON-EXPEDITED			US-UCBSA-2018055688		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Cimzia			S		Unk		Not Reported
	Vitamin D			C				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17302264	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013796			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Arava			S	Unknown	Unk		Sanofi
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Alendronate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Prednisone			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17308071	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013870			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Arava			S	Unknown			Sanofi
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Sanofi
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Methotrexate			S	Oral	Unk, Qw		Not Reported
	Myochrysine			S	Intramuscular	25 Mg, Qw		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17315938	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013861		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Arava			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown			Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi

	Sulfasalazine			S	Unknown	Unk			Not Reported
	Enbrel			S	Subcutaneous	Unk			Not Reported
	Gold			S	Unknown	Unk			Not Reported
	Humira			S	Subcutaneous				Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Simponi			S	Subcutaneous	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17333490	EXPEDITED (15-DAY)		HO	CA-ROCHE-2529931		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Headache; Hepatic Cyst; Hepatic Haematoma; Hepatitis B Core Antibody Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Neutropenia; Pulmonary Mass; Pyrexia; Renal Cyst	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Isoniazid			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Zostavax			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17376781	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531725			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Loss Of Personal Independence In Daily Activities; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Leflunomide			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17416777	EXPEDITED (15-DAY)		OT	US-SA-2020SA038806		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Pain In Extremity; Pleural Effusion; Rheumatoid Arthritis; Rheumatoid Arthritis; Skin Infection	Arava			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17433130	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0820		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Back Disorder; Condition	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S				Not Reported

Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Fatigue; Infiltration Anaesthesia; Joint Arthroplasty; Knee Arthroplasty; Mouth Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Product Use Issue; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Treatment Failure; Vasculitic Rash	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg (Previously)	Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	Cyclical	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Hydroxychloroquine	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral	12.5 Mg Daily	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg Daily	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Neoral	S	Oral		Not Reported
	Neoral	S	Subcutaneous		Not Reported
	Remicade	S			Not Reported
	Rituximab	S	Intravenous (not		Not Reported

			otherwise specified)		
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	C	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17450107	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-BIOVITRUM-2020CA0815		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Drug Specific Antibody Present; Gastroenteritis Viral; Human Anti-Human Antibody Test; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Intentional Product Use Issue; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic	Kineret			S	Subcutaneous			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S				Not Reported
	Apo-Naproxen			S				Not Reported
	Apo-Naproxen			S				Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg 1x1 Daily		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg 1x1 Daily		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	1.5 Mg 1x1 Daily		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Immunoglobulins [Immunoglobulin Human Normal]			S	Intravenous (not otherwise specified)			Not Reported

Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Product Use In Unapproved Indication; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Immunoglobulins [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)		Not Reported
	Immunoglobulins [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Naproxen Sodium	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral	1.3 Mg 2x1 Daily	Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S			Not Reported
	Triamcinolone	S	Subcutaneous		Not Reported

Triamcinolone	S	Intra-articular		Not Reported
Triamcinolone	S	Unknown		Not Reported
Triamcinolone	S			Not Reported
Gammagard Liquid Also Know As Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
Gammagard Liquid Also Know As Immune Globulin (Human)	S			Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Apo Prednisone	S	Oral		Not Reported
Apo Prednisone	S	Oral		Not Reported
Apo Prednisone	S	Oral		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Etanercept	S	Subcutaneous	12.5 Mg 1x1 Week	Not Reported
Etanercept	S	Subcutaneous		Not Reported
Gamastan	S	Intramuscular		Not Reported
Immune Globulin (Immunoglobulins Nos)	S	Unknown		Not Reported
Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)		Not Reported
Immune Globulin (Immunoglobulins Nos)	S	Unknown		Not Reported
Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)		Not Reported
Naproxen	S	Unknown		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Triamcinolone Hexacetonide	C	Unknown		Not Reported
Triamcinolone Acetonide	C	Intra-articular		Not Reported

	Triamcinolone Acetonide	C	Unknown		Not Reported
	Triamcinolone Acetonide	C	Oral		Not Reported
	Triamcinolone Acetonide	C	Intra-articular		Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17580229	EXPEDITED (15-DAY)		DS, OT	CA-BIOVITRUM-2020CA1335		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Foot Operation; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Limb Discomfort; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Methotrexate	S	Subcutaneous	Dose: 17.5 Mg	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Plaquenil	S	Oral		Not Reported
Plaquenil	S	Oral		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Risedronate Sodium	S	Oral		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous		Not Reported
Xeljanz	S	Oral		Not Reported
Risedronate	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Hydroxychloroquine	S			Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Risedronate	C	Unknown		Not Reported
Hydroxychloroquine Sulfate	C			Not Reported
Hydroxychloroquine Sulfate	C			Not Reported
Xeljanz	C	Oral		Not Reported
Methotrexate	C	Unknown	Dose: 17.5 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17591358	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009095		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Supeudol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17633457	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2020CA1653		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S		Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Mycophenolate Mofetil	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S		Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Cellcept	S	Unknown	Not Reported
Plaquenil	S		Not Reported
Sulfasalazine	S		Not Reported
Celebrex	S	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Humira	C	Subcutaneous	Not Reported
Celebrex	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17715753	EXPEDITED (15-DAY)		DE, HO, OT	FR-AUROBINDO-AUR-APL-2020-020591			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Discomfort; Electrocardiogram Qt Prolonged; Loss Of Consciousness; Off Label Use; Ventricular Arrhythmia	Azithromycin			S	Unknown	Unk		Aurobindo
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17721718	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004004071			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Haematochezia; Injection Site Erythema; Injection Site Pain; Injection Site Rash; Musculoskeletal Pain; Osteoarthritis; Product Storage Error; Product Use Issue	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Dupilumab			S	Subcutaneous	600 Mg Once		Not Reported
	Dupilumab			S	Subcutaneous	300 Mg Qow		Not Reported
	Dupilumab			S	Subcutaneous	300 Mg Qow		Not Reported
	Dupilumab Pre-Filled Syringe			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17753736	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010526			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Drug Resistance; Ocular Toxicity; Pain; Rheumatoid Arthritis; Swelling	Leflunomide			S	Oral	10 Mg, Unk		Apotex
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg, Qd		Not Reported

	Plaquenil /00072602/	S	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17754876	EXPEDITED (15-DAY)		DE, OT	BE-SA-2020SA115641		83 YR	Male	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Off Label Use; Product Use Issue; Respiratory Failure; Wrong Technique In Product Usage Process	Kevzara			S	Intravenous (not otherwise specified)	400 Mg		Sanofi
	Kevzara			S				Sanofi
	Hydroxychloroquine Sulfate			S	Oral	2 Df, Bid		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	1 Df, Bid		Sanofi
	Plaquenil			S	Oral	2 Df, Bid		Sanofi
	Plaquenil			S	Oral	1 Df, Bid		Sanofi
	Plaquenil			S	Oral	1 Df, Bid		Sanofi
	Azithromycin			C	Oral	250 Mg, Qd		Not Reported
	Sodium Chloride			C	Subcutaneous	Unk		Not Reported
	Sodium Chloride			C				Not Reported
	Cefuroxime			C		1 Df, Tid		Not Reported
	Clopidogrel Sandoz [Clopidogrel]			C		75 Mg		Not Reported
	Inderal			C		40 Mg, Qd		Not Reported
	Perindopril			C		4 Mg, Qd		Not Reported
	Morphine Hydrochloride			C	Intravenous bolus	2 Mg, Q4h		Not Reported
	Sodium Chloride			C	Intravenous bolus	2 Mg, Q4h		Not Reported
	Dafalgan Forte			C	Oral	Unk Unk, Q6h		Not Reported
	Dafalgan Forte			C				Not Reported
	Dafalgan Forte			C				Not Reported
	Paracetamol B Braun			C	Intravenous drip	3 Df		Not Reported
	Clexane			C	Subcutaneous	60 Mg, Bid		Not Reported
	Simvastatine			C	Oral	1 Df		Not Reported
	Pantomed [Pantoprazole			C	Oral	1 Df, Qd		Not Reported

Sodium Sesquihydrate]				
Pantomed [Pantoprazole Sodium Sesquihydrate]	C	Intravenous bolus	1 Df, Bid	Not Reported
Basaglar	C	Subcutaneous	22 U, Qd	Not Reported
Basaglar	C	Subcutaneous	18 U, Bid	Not Reported
Novorapid	C	Subcutaneous	Unk	Not Reported
Haldol [Haloperidol]	C	Oral	5 Gtt Drops, Qd	Not Reported
Midazolam B Braun	C	Intravenous bolus	5 Mg	Not Reported
Sodium Chloride	C	Intravenous bolus	Unk	Not Reported
Remergon	C	Oral	1 Df, Qd	Not Reported
Tamsulosin	C	Oral	1 Df, Qd	Not Reported
Ciproxin [Ciprofloxacin Hydrochloride]	C		2 Df, Qd	Not Reported
Cymbalta	C	Oral	1 Df	Not Reported
Coversyl [Perindopril Erbumine]	C	Oral	1 Df	Not Reported
Asaflow	C	Oral	1 Df	Not Reported
Contramal	C	Oral	1 Df	Not Reported
Sildenafil Sandoz	C	Oral	0.5 Df	Not Reported
Zocor	C	Oral	1 Df	Not Reported
Mirtazapine	C		15 Mg	Not Reported
Lantus	C		22 Iu	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17758914	EXPEDITED (15-DAY)		OT	CA-ROCHE-1748937		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 3 Months		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 2 Months		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 3 Months		Not Reported

Methotrexate Sodium	S	Oral		Not Reported
Methotrexate Sodium	S	Oral	Therapy Duration: 16.0 Year(S)	Not Reported
Methotrexate Sodium	S	Subcutaneous	Therapy Duration: 16.0 Year(S)	Not Reported
Neoral	S	Subcutaneous	Therapy Duration 15 Years	Not Reported
Neoral	S	Oral		Not Reported
Neoral	S	Subcutaneous	Therapy Duration: 16.0 Year(S)	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Subcutaneous	Therapy Duration: 15 Years	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Therapy Duration: 16.0 Year(S)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 11 Years	Not Reported
Cyclosporine	S	Unknown		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous	Therapy Duration: 3.0 Month(S)	Not Reported
Orencia	S	Subcutaneous	Therapy Duration: 10.0 Months	Not Reported
Orencia	S	Subcutaneous	Therapy Duration: 3.0 Month(S)	Not Reported
Leflunomide	S	Unknown		Not Reported
Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17826236	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-247563		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective For Unapproved Indication	Hydroxychloroquine		S	Unknown	Unk	Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17826324	EXPEDITED (15-DAY)		OT	CA-ROCHE-2607145		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Psoriatic Arthropathy; Synovitis	Rituximab			S	Unknown			Not Reported
	Apremilast			S	Unknown			Not Reported
	Cimzia			S	Unknown	Single-Use Prefilled Syringe		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Otezla			S	Oral			Not Reported
	Otezla			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Benzylpenicillin			C	Unknown			Not Reported
	Infliximab			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17826483	EXPEDITED (15-DAY)		OT	CA-ROCHE-2604951			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use; Prescribed Underdose	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17826546	EXPEDITED (15-DAY)		OT	CA-ROCHE-2607098		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cartilage Atrophy; Drug Ineffective; Joint Swelling; Nausea; Nephrotic Syndrome; Periorbital Oedema; Renal Disorder; Skin Erosion; Therapeutic Product Effect Decreased; Wrist Deformity	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Leflunomide			C	Oral			Not Reported
	Naproxen			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17826617	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-202005005469			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Hypokinesia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Daily Dosage: 200mg/400mg		Concordia
	Fluconazole			S	Unknown	Unk		Not Reported
	Dobutamine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17826772	EXPEDITED (15-DAY)		DE, OT	US-ADVANZ PHARMA-202005005590			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Multiple Organ Dysfunction Syndrome; Off Label Use; Renal Failure	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S		400 Mg, Bid (Day 0)		Concordia
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S		400 Mg, Bid (Days 1-4)		Concordia
	Tacrolimus			S	Unknown	6 Mg, Bid		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	400 Mg		Not Reported
	Lopinavir/Ritonavir			S		400 Mg, Bid (For 5 Days)		Not Reported
	Micafungin			S		100 Mg, Qd		Not Reported
	Sulfamethoxazole-Trimethoprim-Ds			S		Unk		Not Reported
	Heparin			S				Not Reported
	Tobramycin			S		Unk		Not Reported
	Mycophenolic Acid			S		360 Mg, Bid		Not Reported
	Linezolid			S		Unk		Not Reported
	Cefepime			C		Unk		Not Reported
	Vancomycin			C				Not Reported
	Oseltamavir			C		Unk		Not Reported
	Ivig			C	Intravenous (not	10 G		Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17826775	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005592			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphopenia; Toxicity To Various Agents	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17826838	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005793			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoxia; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Cyclosporine			C		100 Mg, Bid (Goal Trough 75-100 Ng/Ml)		Not Reported
	Mycophenolate Mofetil			C		250 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17826909	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202005005611			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Off Label Use	Hydroxychloroquine			S	Unknown	Unk, Coated Tablet		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17827028	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600632			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia;	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Hand Deformity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Sulfasalazine	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Fosamax	S	Oral	Not Reported
	Fosamax	S		Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17827186	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605529		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Cimzia	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	5.0 Months	Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Kevzara	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Mefenamic Acid	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Simponi	S	Unknown	6.0 Months	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Folic Acid	C			Not Reported
	Metformin	C	Unknown		Not Reported
	Rabeprazole Sodium	C	Oral		Not Reported
	Synthroid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17827283	EXPEDITED (15-DAY)		HO, OT	RU-SA-2020SA135428		28 YR	Female	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During	Clexane			S		Unk Unk, Bid		Sanofi

Pregnancy; Iron Deficiency Anaemia; Placental Disorder; Placental Insufficiency; Pre-Eclampsia	Prednisone	S	Unk Unk, Q3h	Not Reported
	Methylprednisolone	S	Unk Unk, Q12h	Not Reported
	Plaquenil	S	Unk Unk, Bid	Sanofi
	Nifedipine	S	90 Mg, Qd	Not Reported
	Methyldopa	S	Unk Unk, Q6h	Not Reported
	Omeprazole	S	Unk Unk, Bid	Not Reported
	Levothyroxine Sodium	S		Not Reported
	Progesterone	S	400 Unk, Qd	Not Reported
	Azathioprine	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17827300	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602408		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alanine Aminotransferase Increased; Alopecia; Anxiety; Arthralgia; Aspartate Aminotransferase Increased; Asthenia; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 20.0		Not Reported

			Years	
Methotrexate	S	Unknown		Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 3.0 Months	Not Reported
Orencia	S	Subcutaneous		Not Reported
Prednisone	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 12.0 Months	Not Reported
Simponi	S	Subcutaneous		Not Reported
Xeljanz	S	Oral	Therapy Duration: 2.0 Months	Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Unknown		Not Reported
Acetaminophen	C			Not Reported
Cetirizine Hydrochloride	C			Not Reported
Cortisone	C			Not Reported
Desoximetasone	C			Not Reported
Dexamethasone	C			Not Reported
Gabapentin	C			Not Reported
Paracetamol	C			Not Reported
Reactine [Cetirizine Hydrochloride]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17827314	EXPEDITED (15-DAY)		OT	BN-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-247483		60 YR	Female	BRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bundle Branch Block Right; Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17827322	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131185			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Arava			S	Unknown			Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi
	Methotrexate			S	Subcutaneous	250 Mg		Not Reported
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	100 Mg		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown	5 Mg, Bid		Not Reported
	Hydroxychloroquine			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17827324	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131118			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Leflunomide			S	Oral			Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, 1 Every 1 Week		Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, 1 Every 1 Day		Sanofi

Sarilumab	S	Subcutaneous	20 Mg, 1 Every 2 Weeks		Sanofi
Azathioprine	S	Unknown			Not Reported
Ciclosporin	S	Unknown			Not Reported
Actemra	S	Subcutaneous	162 Mg, 1 Every 1 Week		Not Reported
Enbrel	S	Unknown			Not Reported
Ergocalciferol	C	Unknown			Not Reported
Esomeprazole	C	Unknown			Not Reported
Magnesium	C	Unknown			Not Reported
Metformin	C	Unknown			Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17827325	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131172			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma	Arava			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	100 Mg		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Amoxil [Amoxicillin]			C	Unknown	Unk		Not Reported
	Amoxicillin Trihydrate;Clavulanate Potassium			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17827327	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131066		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Leflunomide			S	Unknown	Unk		Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Meloxicam			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	160 Mg, Qw		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Depo-Medrol			C	Unknown	80 Mg, Qd		Not Reported
	Diclofenac			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Pantoprazole Magnesium			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C	Oral	5 Mg, (2 Every 1 Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17827361	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131242			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Musculoskeletal Stiffness; Pain In Extremity;	Arava			S	Oral	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi

Rheumatoid Arthritis	Methotrexate	S	Oral	15 Mg, Qw		Not Reported
	Levothyroxine Sodium	S	Oral	175 Mg, Qd		Not Reported
	Prednisone	C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17827363	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131316		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Viral Upper Respiratory Tract Infection	Leflunomide			S	Unknown	20 Mg		Sanofi
	Celecoxib			S	Unknown	200 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Methotrexate			S	Subcutaneous	Unk Unk, Qw		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Qw		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			C	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17827364	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131199			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder	Leflunomide			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

	Hydroxychloroquine Sulfate			S	Unknown	Unk			Sanofi
	Remicade			S	Unknown	Unk			Not Reported
	Rituximab			S	Intravenous drip	Unk			Not Reported
	Humira			S	Subcutaneous	Unk			Not Reported
	Enbrel			S	Unknown	Unk			Not Reported
	Desoximetasone			C	Unknown	Unk			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17827450	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131500		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Arava			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17827568	EXPEDITED (15-DAY)		OT	ES-SA-2020SA135372		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg Day		Sanofi
	Hydroxychloroquine			S				Sanofi

Azithromycin	S	Oral	500 Mg Day		Not Reported
Enoxaparin Sodium	S	Subcutaneous	60 Mg		Sanofi
Roactemra	S	Intravenous (not otherwise specified)	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17827635	EXPEDITED (15-DAY)		DE, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-247555		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Multiple Organ Dysfunction Syndrome	Hydroxychloroquine			S	Unknown	Unk		Sun
	Hydroxychloroquine			S				Sun
	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported
	Lopinavir/Ritonavir			S				Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Tocilizumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17827643	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2020CA2713		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Angiopathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Infection; Pneumonia; Post Procedural Contusion; Rheumatoid Arthritis; Venous Injury; Visual Impairment	Kineret			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17827768	NON-EXPEDITED			NVSC2020US143358			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17828357	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1051051		42 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	250 Milligram, Qd		Not Reported
	Hydroxyzine Hydrochloride			S	Intravenous (not otherwise specified)	25 Milligram, Q6h		Mylan
	Plaquenil /00072603/			S	Oral	200 Milligram, Bid, 12 Hrs		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17828429	EXPEDITED (15-DAY)		LT	ES-ACCORD-183232		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Intrusive Thoughts; Off Label Use; Suicide Attempt	Hydroxychloroquine			S	Oral	200 Mg Every 12 Hours		Not Reported
	Levofloxacin			C	Unknown			Not Reported
	Cortic			C	Intravenous bolus	Bolus Corticosteroids Iv		Not Reported
	Septrin			C	Unknown			Not Reported
	Kaletra			C	Oral			Not Reported
	Acetylcysteine			C	Unknown			Not Reported
	Ciclosporin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17828519	NON-EXPEDITED			US-PFIZER INC-2020207672			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Nodal Osteoarthritis; Peripheral Swelling	Methotrexate Sodium			S		Unk		Pfizer
	Leflunomide			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17828576	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605551			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pulmonary Toxicity	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17828583	EXPEDITED (15-DAY)		LT	CA-ROCHE-2606927			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Meningitis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Visual Impairment	Actemra			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Indometacin			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17828703	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202005005364			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arterial Occlusive Disease; Off Label Use; Pollakiuria; Prostatic Disorder; Tooth Loss	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk,Coated Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17828732	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601838		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alanine Aminotransferase Increased; Alopecia; Anxiety; Arthralgia; Aspartate Aminotransferase Increased; Asthenia; Depression; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Prednisone	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Xeljanz	S	Oral	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Cetirizine Hydrochloride	C	Unknown	Not Reported
	Gabapentin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17828930	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605564		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Burning Sensation; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Kevzara			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Rabeprazole Sodium	S	Oral	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17829374	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-247397		51 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Porphyria	Hydroxychloroquine			S	Unknown	400 Milligram, Daily		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17829520	EXPEDITED (15-DAY)		OT	CA-ROCHE-2604568		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Hair Follicle Tumour Benign; Lymphoproliferative Disorder; Off Label Use; Product Use In Unapproved Indication	Nutropin			S	Subcutaneous			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Amlodipine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Azathioprine			S				Not Reported
	Calcium Carbonate			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S				Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Enalapril			S	Unknown			Not Reported

	Ferric Hydroxide Polymaltose Complex	S	Unknown	Not Reported
	Ferrous Fumarate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Insulin	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Metformin	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Methotrexate	S		Not Reported
	Prednisone	S	Unknown	Not Reported
	Protropin	S	Intramuscular	Not Reported
	Ranitidine	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Remicade	S		Not Reported
	Sulfamethoxazole	S	Unknown	Not Reported
	Testosterone	S	Unknown	Not Reported
	Acetazolamide	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17829521	EXPEDITED (15-DAY)		DE, OT	ES-ROCHE-2607349		21 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hepatitis; Hypocoagulable State; Pancreatitis Acute	Tocilizumab			S	Intravenous (not otherwise specified)	Desconocida		Not Reported
	Tocilizumab			S				Not Reported
	Ambisome			S	Intravenous (not otherwise specified)			Not Reported
	Hidroxicloroquina Sulfato			S	Oral	400mg/24h		Not Reported
	Hidroxicloroquina Sulfato			S				Not Reported

	Linezolid	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17829594	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1051133		31 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic; Off Label Use	Lopinavir/Ritonavir Mylan			S	Oral	4 Dosage Form		Mylan
	Plaquenil /00072603/			S	Oral	100 Milligram, Qd		Mylan
	Calcidose /07357001/			C		Unk		Mylan
	Piperacilline/Tazobactam			C		Unk		Mylan
	Doliprane			C		Unk		Mylan
	Rocephine			C		Unk		Mylan
	Sodium Bicarbonate			C		Unk		Mylan
	Furosemide			C		Unk		Mylan
	Amlodipine			C		Unk		Mylan
	Diffu K			C		Unk		Mylan
	Renvela			C		Unk		Mylan
	Calciparine			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17829602	EXPEDITED (15-DAY)		CA, OT	FR-MYLANLABS-2020M1051130			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Achromotrichia Congenital; Foetal Exposure During Pregnancy	Parlodel			S	Transplacental	20 Milligram, Qd		Mylan
	Hydrocortisone Roussel /00028601/			S	Transplacental	100 Milligram, Qd		Mylan
	Zithromax			S	Transplacental	250 Milligram, Qd		Mylan
	Plaquenil /00072603/			S	Transplacental	600 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17829606	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2020M1051120		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Thrombocytopenia	Azithromycin			S	Oral	500 Milligram, Qd (500 Mg Dia)		Not Reported
	Enoxaparin			S	Subcutaneous	80 Milligram, Bid (80 Mg Cada 12h)		Not Reported
	Roactemra			S	Intravenous (not otherwise specified)	600 Milligram, Qd (600 Mg)		Mylan
	Hidroxicloroquina /00072601/			S	Oral	400 Milligram, Qd (400 Mg Dia)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17829680	EXPEDITED (15-DAY)		OT	BR-PFIZER INC-2020204768		60 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
	Zitromax			S	Oral	500 Mg, 1x/Day		Pfizer
	Reuquinol			S	Oral	400 Mg, Daily ((Given In 2 Divided Doses Every 12 Hours)		Not Reported
	Reuquinol			S		400 Mg, Daily (Given In 2 Divided Doses Every 12 Hours)		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 G, 2x/Day		Not Reported
	Oseltamivir			C	Oral	75 Mg, 2x/Day		Not Reported
	Tazocin			C	Intravenous (not otherwise specified)	2.25 G, 3x/Day (Every 8 Hours)		Not Reported
	Tazocin			C	Intravenous (not	4.5 G, 4x/Day (Every		Not Reported

		otherwise specified)	6hours)	
Vancomycin Hydrochloride	C	Intravenous (not otherwise specified)	1 G, 2x/Day (Every 12hours)	Not Reported
Vancomycin Hydrochloride	C	Intravenous (not otherwise specified)	1 G, 1x/Day	Not Reported
Dobutamine	C		Unk	Not Reported
Sodium Bicarbonate	C		Unk	Not Reported
Cis [Cisatracurium Besilate]	C	Intravenous (not otherwise specified)	100 Mg, As Needed	Not Reported
Potassium Chloride	C	Intravenous (not otherwise specified)	40 Mg	Not Reported
Sodium Chloride	C		Unk	Not Reported
Dopacris	C	Intravenous (not otherwise specified)	250 Mg, As Needed	Not Reported
Dormire [Midazolam Hydrochloride]	C	Intravenous (not otherwise specified)	100 Mg, As Needed	Not Reported
Hemofol	C	Subcutaneous	5000 Iu, 2x/Day (Every 12 Hours)	Not Reported
Nexium Mups [Esomeprazole Magnesium]	C		20 Mg, 1x/Day	Not Reported
Lipless	C		Unk	Not Reported
Hydrochlorothiazide	C		Unk	Not Reported
Trezor [Rosuvastatin Calcium]	C		Unk	Not Reported
Metformin	C		Unk	Not Reported
Losartan	C		Unk	Not Reported
Tamiram	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17829730	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2606587		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Arthropathy;	Actemra			S	Intravenous (not			Not Reported

Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present; Gastroenteritis Viral; Human Anti-Human Antibody Test; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting			otherwise specified)	
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Naproxen	S	Unknown	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not	Not Reported

		otherwise specified)	
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Triamcinolone	S	Unknown	Not Reported
Triamcinolone Acetonide	S	Intramuscular	Not Reported
Triamcinolone Acetonide	S	Intra-articular	Not Reported
Triamcinolone Hexacetonide	S	Other	Not Reported
Triamcinolone Hexacetonide	S	Unknown	Not Reported

	Folic Acid	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17829735	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Heart Rate Increased; Hypertension; Nervousness; Panic Attack	Hydroxychloroquine			S				Dr Reddys

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17829746	DIRECT		DS, OT			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease; Gingival Erosion; Tooth Disorder; Tooth Fracture	Orencia 125 Mgs	Y		S	Subcutaneous	Quantity:1 Injection(S);Other Frequency:Once A Week;		Unknown
	Hydroxychloroquine	Y		S	Oral	Quantity:1 Capsule(S);		Prasco
	Morphine 30mg			C				Not Reported
	Oxycodone			C				Not Reported
	Iron Tablets Tablet			C				Not Reported
	Spiriva Respimat 2.5mg			C				Not Reported
	Cetirizine 10mg			C				Not Reported
	Topiramate 100mg			C				Not Reported
	Aspirin 81mg			C				Not Reported
	Lisinopril 5mg			C				Not Reported
	Folic Acid 1mg			C				Not Reported
	Prednisone 4mgs			C				Not Reported
	Calcium 600mgs			C				Not Reported
	Vitamin A			C				Not Reported
	Vitamin D3			C				Not Reported
	Vitamin B 12			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17829863	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE			Unknown	ESP

LIMITED-ES-ZYDUS-051271

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hyponatraemia	Azithromycin			S	Oral	500 Mg Dia		Zydus Pharm
	Ceftriaxona [Ceftriaxone]			S	Intravenous (not otherwise specified)	2 Gr		Not Reported
	Symbicort			S	Respiratory (inhalation)	2-2-2		Not Reported
	Hidroxicloroquina [Hydroxychloroquine]			S	Oral	400 Mg Dia		Not Reported
	Salbutamol			S	Respiratory (inhalation)	2-2-2 Inh		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17829864	EXPEDITED (15-DAY)		OT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-051272			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Hypocoagulable State; Hypofibrinogenaemia; Thrombocytopenia	Azithromycin			S	Oral	500 Mg Dia		Zydus Pharm
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Hidroxicloroquina [Hydroxychloroquine]			S	Oral	400 Mg Dia		Not Reported
	Dexametasona [Dexamethasone]			S	Intravenous (not otherwise specified)	20 Mg		Not Reported
	Ceftriaxona [Ceftriaxone]			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported
	Enoxaparina			S	Subcutaneous	80 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17829970	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201805-001826			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qod		Concordia
	Tacrolimus Monohydrate			S	Oral	4 Mg, Qd		Not Reported
	Prednisolone			C		Unk		Not Reported
	Onealfa			C		Unk		Not Reported
	Onealfa			C				Not Reported
	Aspartate Comps			C		Unk		Not Reported
	Aspartate Comps			C				Not Reported
	Takepron			C		Unk		Not Reported
	Bayaspirin			C		Unk		Not Reported
	Warfarin			C		Unk		Not Reported
	Avapro			C		Unk		Not Reported
	Metgluco			C		Unk		Not Reported
	Myslee			C		Unk		Not Reported
	Hyalein Eye Drops			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17830009	EXPEDITED (15-DAY)		HO, OT	FR-ASTRAZENECA-2020SE66003		69 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Coronavirus Infection; Drug Ineffective; Hepatic Function Abnormal; Hypoxia; Inflammation; Localised Oedema; Pneumonia;	Inexium			S	Intravenous (not otherwise specified)	40 Mg, Qd		Astrazeneca
	Tazocilline			S	Unknown	Unk		Not Reported
	Perfalgan			S	Unknown	1 G, Qid If Temprature Is Greater To 38.24.0g Unknown		Not Reported
	Lovenox			S	Subcutaneous	Unk Unk, Bid (8000 Ui)		Not Reported
	Bactrim			S	Unknown	Unk		Not Reported
	Rocephine			S	Unknown	Unk		Not Reported

Pseudomonas Infection; Quarantine; Severe Acute Respiratory Syndrome; Spinal Disorder; Stenotrophomonas Infection	Mucomyst		S	Unknown	1 Df, Qid (Sachet Sng)4.0df Unknown	Not Reported
	Dextro [Dextromethorphan Hydrobromide]		S	Unknown	Unk	Not Reported
	Catapressan		S	Unknown	Unk	Not Reported
	Claventin [Clavulanic Acid/Ticarcillin]		S	Unknown	Unk	Not Reported
	Lederfoline		S	Unknown	Unk	Not Reported
	Tavanic		S	Unknown	500 Mg, Bid	Not Reported
	Eupressyl		S	Unknown	Unk	Not Reported
	Fortum		S	Unknown	2 G, Tid	Not Reported
	Zithromax		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Tranxene		S	Unknown	2.5 Mg Pre Hour	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17830033	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005516			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Lupus Nephritis; Off Label Use; Proteinuria; Treatment Noncompliance	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Prednisone			S	Unknown	Unk		Not Reported
	Lovenox			S	Unknown	Unk		Not Reported
	Sulfamethoxazole/Trimethoprim			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17830092	EXPEDITED (15-DAY)		DS	CA-ROCHE-2599257		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Pregnancy; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Actemra	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Arava	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfathalidine	S	Oral	Not Reported
	Sulfathalidine	S	Oral	Not Reported

	Tofacitinib	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Topicort [Desoximetasone]	S	Cutaneous	Not Reported
	Alendronate Sodium	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17830175	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2020M1052059		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Intentional Overdose; Tachycardia	Hydroxychloroquine			S	Oral	Approximately 10-11 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17830229	EXPEDITED (15-DAY)		OT	NVSC2020CA143801			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angiopathy; Drug Ineffective; Panniculitis	Colchicine			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Novartis
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Gen-Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17830313	EXPEDITED (15-DAY)		OT	FR-009507513-2005FRA006026		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Celestene Chronodose			S	Intravenous (not	1 Dosage Form, Qd (5,70		Merck

				otherwise specified)	Mg/Ml, Suspension Injectab)	
	Ceftriaxone Sodium		S	Intravenous (not otherwise specified)	1 Gram, Qd	Not Reported
	Zithromax		S	Oral	250 Milligram, Qd	Not Reported
	Plaquenil		S	Oral	600 Milligram, Qd	Not Reported
	Lovenox		C		Unk, Mammal/Pork/Intestinal Mucosa	Not Reported
	Potassium Acetate		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17830468	EXPEDITED (15-DAY)		OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2020VAL000434			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Demerol			S	Unknown	Unk		Validus
	Pethidine Hydrochloride			S	Unknown	Unk		Validus
	Prednisone			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Bisoprolol			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Metronidazole			S	Unknown	Unk		Not Reported
	Norfloxacin			S	Unknown	Unk		Not Reported
	Plaquenil /00072603/			S	Oral	400 Mg, Unk		Not Reported

	Levofloxacin	S	Unknown	Unk	Not Reported
	Arthrotec	S	Unknown	Unk	Not Reported
	Arthrotec	S	Intracardiac	Unk	Not Reported
	Ceclor	S	Unknown	Unk	Not Reported
	Celebrex	S	Oral	200 Mg, Qd	Not Reported
	Humira	S	Subcutaneous	400 Mg, Unk	Not Reported
	Lyrica	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17830774	EXPEDITED (15-DAY)		HO	CA-JNJFOC-20200525219		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

Rituximab	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Ciclosporin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17830784	EXPEDITED (15-DAY)		HO	CA-JNJFOC-20200526261		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Codeine			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17830922	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1051633		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Azithromycin			S		500 Milligram, Qd		Not Reported
	Kaletra			S		1 Dosage Form, Bid		Mylan
	Interferon Beta			S		250 Milligram, Q2d		Mylan
	Hidroxicloroquina /00072601/			S		200 Milligram, Bid		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17832245	EXPEDITED (15-DAY)		HO	CA-ROCHE-2605648		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	10657398	EXPEDITED (15-DAY)		DS	FR-ASTRAZENECA-2014SE95951		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Peripheral Sensorimotor Neuropathy	Inexium			S	Oral			Astrazeneca
	Fosamax			S	Oral			Not Reported
	Tahor			S	Oral			Not Reported
	Lexomil Roche			S	Oral			Not Reported
	Cacit Vitamine D3			S	Oral			Not Reported
	Rivotril			S	Oral			Not Reported
	Cymbalta			S	Oral			Not Reported
	Avodart			S	Oral			Not Reported
	Lasilix			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Forlax			S	Oral			Not Reported
	Metoject			S	Subcutaneous			Not Reported
	Skenan			S	Oral			Not Reported

	Cortancyl			S	Oral					Not Reported
	Salazopyrine			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	12676043	EXPEDITED (15-DAY)		DS, OT	CA-SA-2015SA146389		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Arava			S	Oral	20 Mg, Unk		Sanofi
	Leflunomide			S	Oral	Unk		Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Plaquenil			S	Oral	400 Mg,Qd		Sanofi
	Plaquenil			S	Oral	1 Df, Qd		Sanofi
	Methotrexate			S	Oral	25 Mg,Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate			S	Oral	1 Df, Qd		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Mg, Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	4000 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Pseudoephedrine Hydrochloride			S	Unknown	25 Mg, Unk		Sanofi
	Desoximetasone			S	Oral	Unk		Sanofi
	Desoximetasone			S	Oral	Unk		Sanofi
	Desoximetasone			S	Cutaneous	Unk		Sanofi

Alendronate Sodium	S	Oral	Unk	Not Reported
Alendronate Sodium	S		Unk	Not Reported
Alendronate Sodium	S	Oral	Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Sanofi
Hydrocortisone Acetate	S	Subcutaneous	Unk	Sanofi
Hydrocortisone Acetate	S	Unknown	Unk	Sanofi
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1 G,Bid	Not Reported
Sulfasalazine	S	Unknown	500 Mg	Not Reported
Sulfasalazine	S		1 G, 1 In 12 Hours	Not Reported
Sulfasalazine	S	Oral	2 Df, Qd	Not Reported
Paracetamol	S	Unknown	Unk	Not Reported
Cortisone Acetate	S	Unknown	25 Mg, Unk	Not Reported
Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	25 Mg, Unk	Not Reported
Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	10 Mg, Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Sanofi
Hydroxychloroquine	S	Oral	Unk	Sanofi
Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
Folic Acid	S	Unknown	1 Mg, Unk	Not Reported
Folic Acid	S	Unknown	5 Mg	Not Reported
Folic Acid	S	Unknown	25 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported

Actemra	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Cortisone	S	Oral	Unk Unk,Prn	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
Enbrel	S	Subcutaneous	Unk, Prn	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Golimumab	S	Subcutaneous	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Xeljanz	S		Unk	Not Reported
Xeljanz	C	Unknown	5 Mg, Bid	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Atasol [Paracetamol]	C	Unknown	Unk	Not Reported
Salazopyrin	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	12864344	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1717965			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Glucose Increased; Blood Pressure Increased; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Femur Fracture; Gait Disturbance; Gastric Disorder; Glycosylated Haemoglobin Increased; Heart Rate Increased; Hepatic Enzyme Increased; Infection; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphocyte Count Increased; Malaise; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Nausea; Nephrolithiasis; Neutrophil Count Increased; Off Label Use; Osteopenia; Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Pyrexia; Rash; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Somnolence; Somnolence; Synovitis;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Therapy Duration: 4 Months		Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	On 10/Feb/2016, She Received Last Dose Of Etanercept (Enbrel)		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tylenol			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Tooth Abscess; Treatment Failure; Visual Impairment; Weight Decreased; White Blood Cell Count Increased	Hydroxychloroquine Sulfate		S	Subcutaneous		Not Reported
	Acetaminophen		S	Unknown		Not Reported
	Acetaminophen		S	Unknown		Not Reported
	Diphenhydramine Hydrochloride		S	Unknown		Not Reported
	Diphenhydramine Hydrochloride		S			Not Reported
	Apo-Acetaminophen		S	Unknown		Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Doxycycline Hyclate		S	Unknown		Not Reported
	Apo-Prednisone		S	Unknown		Not Reported
	Apo-Hydro		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Methotrexate		C	Unknown	25 Mg/Ml	Not Reported
	Meloxicam		C			Not Reported
	Synthroid		C			Not Reported
	Tylenol		C			Not Reported
	Acetaminophen;Codeine Phosphate		C	Unknown	As Required	Not Reported
	Celebrex		C	Oral		Not Reported
	Hydromorphone Hydrochloride		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	13058844	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015725		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; Fracture; General Physical Health Deterioration; Hepatitis; Immobile; Loss Of Personal Independence In Daily Activities; Lower	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Prednisone			S	Unknown	Unk		Apotex
	Apo-Prednisone			S	Oral	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Celecoxib			S	Unknown	Unk		Apotex
	Risedronate			S	Unknown	Unk		Apotex
	Risedronate			S	Oral	Unk		Apotex

Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Sulfasalazine	S	Oral	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Oral	50 Mg, Unk	Not Reported
	Prednisolone	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actonel	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Mg, Qd	Not Reported
	Celebrex	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	20 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Unknown	Unk, Q.Wk.	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Prolia	S	Subcutaneous	Unk	Not Reported
	Prolia	S			Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg, Q.Wk.	Not Reported
	Prednisolone Sodium Phosphate	S	Unknown	Unk	Not Reported
	Prednisolone Sodium Phosphate	S	Ophthalmic	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Cyclobenzaprine	C	Unknown	10 Mg, Unk	Not Reported
	Desoximetasone	C	Unknown	5 Mg, Qd	Not Reported
	Desoximetasone	C	Unknown	5 Mg, Unk	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported

	Prednisone Acetate	C	Unknown	5 Mg, Qd	Not Reported
	Tylenol /00020001/	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	13111870	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1717236			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous	Every Week		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Rho(D) Immune Globulin			S	Unknown			Not Reported
	Humira			S	Subcutaneous	4 Years		Not Reported
	Arava			S	Unknown			Not Reported
	Benzalkonium Chloride			S	Unknown			Not Reported
	Boric Acid			S	Unknown			Not Reported
	Diphenhydramine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Disodium Edetate			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Subcutaneous			Not Reported
	Sodium Borate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Phenylephrine Hcl			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Actemra	S	Unknown			Not Reported
Tofacitinib Citrate	S	Subcutaneous			Not Reported
Tofacitinib Citrate	S	Unknown			Not Reported
Tofacitinib Citrate	S	Unknown			Not Reported
Tofacitinib Citrate	S	Unknown			Not Reported
Methotrexate Sodium	S	Oral	Qwk		Not Reported
Methotrexate Sodium	S	Subcutaneous			Not Reported
Xeljanz	C	Oral			Not Reported
Ibuprofen	C	Oral			Not Reported
Celebrex	C	Oral			Not Reported
Lipitor [Atorvastatin Calcium]	C	Oral			Not Reported
Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	13212360	EXPEDITED (15-DAY)		OT	CA-SA-2015SA111836		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Breast Cancer; Breast Cancer Stage Iii; Condition Aggravated; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Drug Ineffective; Drug Intolerance; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Nausea; Ovarian Cancer; Rheumatoid Arthritis;	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Sodium Aurothiomalate			S	Intramuscular	Unk Unk,Unk		Not Reported
	Methotrexate Bellon			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Rituxan			S	Intravenous (not	Unk Unk,Unk		Not Reported

Rheumatoid Nodule; Sleep Disorder; Therapeutic Product Effect Incomplete; Treatment Noncompliance			otherwise specified)		
	Simponi	S	Subcutaneous		Not Reported
	Gold	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Rituximab	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	13657154	EXPEDITED (15-DAY)		DS, HO, OT	CA-SA-2017SA105779		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling;	Hydroxychloroquine			S	Oral	200 Mg, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg		Sanofi
	Leflunomide			S	Oral	20 Mg		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Sulfasalazine			S		500 Mg		Not Reported
	Alendronate Sodium			S	Unknown	70 Mg,Qw		Not Reported
	Alendronate Sodium			S	Unknown	Unk Unk,Unk		Not Reported
	Codeine			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg		Not Reported
	Methotrexate			S	Oral	10 Mg,Qw		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Mg		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Mg, Qw		Not Reported
	Methotrexate			S		12 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Qw		Not Reported
	Methotrexate			S		15 Mg		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Q4w		Not Reported
	Methotrexate			S		12.5 Mg, Q4w		Not Reported
	Methotrexate			S		12 Mg		Not Reported

Product Use Issue; Pruritus; Rash; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Ulcer	Methotrexate	S	Subcutaneous	15 Mg, Qw	Not Reported
	Methotrexate	S	Oral	10 Mg, Q4w	Not Reported
	Methotrexate	S		10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Qw	Not Reported
	Methotrexate	S		12.5 Mg, Qw	Not Reported
	Methotrexate	S		10 Mg, Qw	Not Reported
	Methotrexate	S	Oral	10 Mg, Qw	Not Reported
	Methotrexate	S		12.5 Mg, Qw	Not Reported
	Methotrexate	S	Oral	10 Mg, Q4w	Not Reported
	Methotrexate	S		12 Mg, Qw	Not Reported
	Methotrexate	S		12.5 Mg, Qw	Not Reported
	Methotrexate	S		10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	15.5 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	12 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	70 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg, Qw	Not Reported
	Methotrexate	S		17.5 Mg, Qw	Not Reported
	Methotrexate	S		15 Mg, Q4w	Not Reported
	Methotrexate	S		12 Mg, Q4w	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Q4w	Not Reported
	Methotrexate	S	Oral	25 Mg, Qw	Not Reported
	Alendronic Acid	S		70 Mg, Qw	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, Qm	Not Reported
	Myochrysine	S	Intramuscular	25 Mg, Qm	Not Reported
	Myochrysine	S	Parenteral	50 Mg, Qm	Not Reported
	Myochrysine	S	Intramuscular	25 Mg, Qw	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Qow	Not Reported

Actemra	S	Unknown	680 Mg,Qm	Not Reported
Actemra	S	Unknown	360 Mg,Qm	Not Reported
Actemra	S		380 Mg	Not Reported
Actemra	S		360 Mg, Qm	Not Reported
Enbrel	S	Unknown	50 Mg,Biw	Not Reported
Enbrel	S	Unknown	25 Mg,Biw	Not Reported
Enbrel	S		Unk	Not Reported
Enbrel	S		50 Mg, Qw	Not Reported
Humira	S	Subcutaneous	40 Mg,Qow	Not Reported
Humira	S		40 Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
Orencia	S	Unknown	780 Mg,Qw	Not Reported
Orencia	S		780 Mg	Not Reported
Orencia	S		780 Mg, Qw	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
Remicade	S		Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg,Bid	Not Reported
Rituxan	S		Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg,Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg,Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
Rituximab	S		1000 Mg, Bid	Not Reported
Tocilizumab	S		680 Mg, Q4w	Not Reported
Ciclosporin	C	Unknown	150 Mg,Qd	Not Reported

Prednisolone	C	Unknown	10 Mg,Unk		Not Reported
Prednisone	C	Unknown	10 Mg,Qd		Not Reported
Prednisone	C		10 Mg, Qd		Not Reported
Xeljanz	C				Not Reported
Alendronate Sodium	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	16695071	EXPEDITED (15-DAY)		OT	DE-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-079550			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Apixaban			S	Unknown	2.5 Milligram, Bid		Bristol Myers Squibb
	Apixaban			S	Unknown	2 Dosage Form, Qd		Bristol Myers Squibb
	Volibris			S	Oral	30 Milligram, Qd		Not Reported
	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported
	Lyrica			S	Unknown	100 Milligram, Tid		Not Reported
	Quensyl			S	Unknown	40 Mg, Bid (80mg/Day)		Not Reported
	Quensyl			S	Unknown	20 Milligram, Bid		Not Reported
	Roactemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported
	Roactemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported
	Spasmolyt			S	Unknown	30 Milligram, Qd		Not Reported
	Spasmolyt			S	Unknown	30 Milligram, Qd		Not Reported
	Spasmolyt			S	Unknown	15 Milligram, Qd		Not Reported
	Spasmolyt			S	Unknown	1 Dosage Form		Not Reported
	Omeprazole			S	Oral	1 Dosage Form, Bid		Not Reported
	Omeprazole			S	Oral	20 Milligram		Not Reported
	Ramipril			S	Oral	1 Dosage Form, Bid		Not Reported
	Ramipril			S	Unknown	5 Milligram, Qd		Not Reported
	Sildenafil Citrate			S	Unknown	60 Milligram, Daily Dose		Not Reported
	Pregabalin			S	Unknown	100 Milligram, Tid		Not Reported
	Pregabalin			S	Unknown	1 Dosage Form		Not Reported

Ambrisentan	S	Unknown	30 Milligram, Qd		Not Reported
Ambrisentan	S	Oral	1 Dosage Form, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17024269	EXPEDITED (15-DAY)		OT	DE-ADVANZ PHARMA-GSH201908-001839			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Hydroxychloroquine			S	Unknown	20 Mg, Bid (40 Mg/Day)		Concordia
	Hydroxychloroquine			S	Unknown	40 Mg, Bid (80mg/Day)		Concordia
	Ramipril			S	Oral	1 Dosage Form, Bid, (1 - 0 - 1)		Not Reported
	Ramipril			S	Unknown	5 Mg, Qd		Not Reported
	Lyrica			S	Unknown	100 Mg, Tid		Not Reported
	Lyrica			S	Unknown	1 Dosage Form, Tid		Not Reported
	Lyrica			S	Unknown	100 Mg, Tid		Not Reported
	Omeprazole			S	Oral	1 Dosage Form, Bid (1-0-1)		Not Reported
	Omeprazole			S	Oral	20 Mg, Bid		Not Reported
	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported
	Volibris			S	Unknown	30 Mg, Qd		Not Reported
	Volibris			S	Unknown	Unk		Not Reported
	Volibris			S	Unknown	30 Mg, Qd		Not Reported
	Spasmolyt			S	Unknown	30 Mg, Qd		Not Reported
	Spasmolyt			S	Unknown	1 Dosage Form, Qd		Not Reported
	Spasmolyt			S	Unknown	15 Mg, Qd		Not Reported
	Spasmolyt			S	Unknown	30 Mg, Qd		Not Reported
	Apixaban			S	Unknown	2.5 Mg, Bid		Not Reported
	Apixaban			S	Unknown	2 Dosage Form, Qd		Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qw, Solution For Injection In Pre-Filled Syringe		Not Reported

Roactemra	S	Subcutaneous	162 Mg, Qw		Not Reported
Roactemra	S	Subcutaneous	162 Mg, Qw		Not Reported
Sildenafil Citrate	S	Unknown	60 Mg, Qd		Not Reported
Ambrisentan	S	Oral	30 Mg, Qd		Not Reported
Ambrisentan	S	Oral	1 Dosage Form, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17088021	NON-EXPEDITED			US-UCBSA-2018027063			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Cimzia			S				Not Reported
	Methotrexate			S				Not Reported
	Plaquenil			S				Not Reported
	Prednisone			S				Not Reported
	Remicade			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17090199	NON-EXPEDITED			US-UCBSA-2018021530			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Cimzia			S		Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown Dose		Not Reported
	Methotrexate			S		Unknown		Not Reported
	Hydroxychloroquine			S		Unknown		Not Reported
	Leflunomide			S		Unknown Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17104636	NON-EXPEDITED			US-UCBSA-2017051005			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Drug Reaction; Drug Intolerance	Cimzia	S		Unk	Not Reported
	Methotrexate	S		Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S		Unk	Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Tofacitinib	C	Oral	1 Mg, Once Daily (Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17104656	NON-EXPEDITED			US-UCBSA-2018003810		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Butterfly Rash; Drug Ineffective; Gastrointestinal Disorder; Mental Status Changes; Pruritus	Cimzia			S		Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17208175	NON-EXPEDITED			US-UCBSA-2017031305			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia Of Chronic Disease; Blood Prolactin Decreased; Blood Thyroid Stimulating Hormone Decreased; Essential Hypertension; Fall; Fibromyalgia; Gait Disturbance; Immunoglobulins Decreased; Insomnia; Osteoarthritis; Osteopenia; Pain; Rheumatoid Arthritis; Spondyloarthropathy;	Cimzia			S		Unk		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Enbrel			S				Not Reported
	Prolia			S		Unk		Not Reported
	Methotrexate Sodium			S		Unk		Not Reported
	Tofacitinib Citrate			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported

Synovitis; Type V Hyperlipidaemia	Humira	S		40 Mg, Weekly (Qw)	Not Reported
	Humira	S			Not Reported
	Orencia	S		Unk	Not Reported
	Plaquenil	S		Unk	Not Reported
	Arava	S	Oral	20 Mg Daily	Not Reported
	Aranesp	C			Not Reported
	Oxycodone	C			Not Reported
	Abilify	C		Unk	Not Reported
	Advair	C			Not Reported
	Atenolol	C			Not Reported
	Acetylsalicylic Acid	C			Not Reported
	Crestor	C			Not Reported
	Cytomel	C			Not Reported
	Dorzolamide Hcl	C		Unk	Not Reported
	Duloxetine Hydrochloride	C		Unk	Not Reported
	Duoneb	C			Not Reported
	Famotidine	C			Not Reported
	Finasteride	C			Not Reported
	Furosemide	C			Not Reported
	Gabapentin	C			Not Reported
	Leflunomide	C			Not Reported
	Lovaza	C			Not Reported
	Medrol	C			Not Reported
	Myrbetriq	C		Unk	Not Reported
	Nexium	C			Not Reported
	Fish Oil W/Tocopherol	C			Not Reported
	Oxycodone Hcl	C			Not Reported
	Prochlorperazine Maleate	C			Not Reported
	Relpax	C			Not Reported
	Singulair	C			Not Reported
	Soma	C			Not Reported
	Sulfazine Ec	C			Not Reported
	Synthroid	C			Not Reported
	Tamsulosin Hcl	C			Not Reported
	Topamax	C			Not Reported
	Topiramate	C			Not Reported
	Triamterene/Hctz	C			Not Reported
	Voltaren	C			Not Reported
	Xalatan	C			Not Reported

Cymbalta	C		Not Reported
Vicodin	C		Not Reported
Vicodin	C		Not Reported
Klonopin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17235412	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508236			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17259883	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518735			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17285802	EXPEDITED (15-DAY)		OT	CA-ROCHE-2523752		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17288398	EXPEDITED (15-DAY)		HO, LT, OT	CA-SA-2020SA013858		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Ill-Defined Disorder; Infection; Kidney Infection; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Sepsis; Therapeutic Response Decreased	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Oral	4 Df, Qw		Not Reported
	Methotrexate			S	Oral	Qw (1 Every 1 Weeks)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17290629	EXPEDITED (15-DAY)		DE	CA-ROCHE-2528043		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diffuse Large B-Cell Lymphoma	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported
	Prednisone Acetate			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Prednisone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17305038	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013783			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Deformity; Finger Deformity; Foot Deformity; Hand Deformity; Hepatic Failure; Hypersensitivity; Infection; Knee Arthroplasty; Ocular Icterus; Osteoarthritis; Pain; Pancreatitis; Upper Limb Fracture; Wrist Deformity	Arava			S		Unk		Sanofi
	Celecoxib			S		Unk		Not Reported
	Diclofenac Sodium			S		Unk		Not Reported
	Plaquenil			S		Unk		Sanofi
	Sulfasalazine			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Methotrexate			C	Subcutaneous	5 Mg, Qw		Not Reported
	Xeljanz			C		5 Mg, Qod		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17307242	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013790			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Steatosis; Synovitis; Treatment Failure	Leflunomide			S	Unknown	Unk, Stop Date-??-Oct-2009		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Actemra			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17307937	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013792			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hand Deformity; Joint Range Of Motion Decreased; Peripheral Swelling; Therapeutic Product Effect Decreased; White Blood Cell Count Decreased	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Unknown	400 Mg		Sanofi
	Methotrexate			S	Unknown	17.5 Mg, Qw		Not Reported
	Actemra			S	Subcutaneous	162 Mg		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg		Not Reported
	Rituxan			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17309844	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524259			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness;	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Depo-Medrol			C	Unknown	Suspension Intraarticular		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Humira			C	Unknown	Solution Subcutaneous		Not Reported

Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Hydroxychloroquine Sulfate		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17519910	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-07738		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown Single Use Pre-Filled Syringe, Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported

Plaquenil	S	Unknown			Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Xeljanz	C	Unknown	Unknown		Not Reported
Hydroxychloroquine Sulfate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17597116	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-GSH201903-000649			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conjunctivitis Bacterial; Gnathoschisis; Herpes Zoster; White Blood Cell Count Decreased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Valixa			S	Oral	1800 Mg, Qd		Not Reported
	Prograf			S	Oral	3 Mg, Qd		Not Reported
	Prograf			S	Oral	2 Mg, Qd		Not Reported
	Prograf			S	Oral	1.5 Mg, Qd		Not Reported
	Prograf			S	Oral	2 Mg, Qd		Not Reported
	Prednisolone			S	Oral	25 Mg, Qd		Not Reported
	Prednisolone			S	Oral	40 Mg, Qd		Not Reported
	Prednisolone			S	Oral	30 Mg, Qd		Not Reported
	Prednisolone			S	Oral	20 Mg, Qd		Not Reported
	Prednisolone			S	Oral	17.5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	15 Mg, Qd		Not Reported
	Prednisolone			S	Oral	12.5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	10 Mg, Qd		Not Reported
	Prednisolone			S	Oral	9 Mg, Qd		Not Reported
	Prednisolone			S	Oral	8 Mg, Qd		Not Reported
	Prednisolone			S	Oral	7 Mg, Qd		Not Reported
	Prednisolone			S	Oral	6 Mg, Qd		Not Reported

Prednisolone	S	Oral	5 Mg, Qd		Not Reported
Bayaspirin	C		Unk		Not Reported
Rabeprazole Sodium	C		Unk		Not Reported
Rabeprazole Sodium	C				Not Reported
Halizon	C		Unk		Not Reported
Pitavastatin Calcium	C		Unk		Not Reported
Pitavastatin Calcium	C				Not Reported
Alendronate	C		Unk		Not Reported
Alendronate	C				Not Reported
Daiphen	C		Unk		Not Reported
Daiphen	C				Not Reported
Nitrazepam	C		Unk		Not Reported
Evoxac	C		Unk		Not Reported
Magnesium Oxide	C		Unk		Not Reported
Equa	C		Unk		Not Reported
Januvia	C		Unk		Not Reported
Humulin R	C		Unk		Not Reported
Aiphagan	C		Unk		Not Reported
Lumigan	C		Unk		Not Reported
Timoleate	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17609185	EXPEDITED (15-DAY)		HO, LT, OT	CA-ADVANZ PHARMA-GSH201702-001124			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthritis; Arthritis; Arthropathy; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Condition Aggravated;	Hydroxychloroquine			S	Oral	5 Mg/Kg, Qd		Concordia
	Hydroxychloroquine			S		Unk		Concordia
	Adalimumab			S	Unknown	Unknown		Not Reported
	Abatacept			S	Intravenous (not otherwise specified)	250 Mg, Monthly		Not Reported
	Actemra			S	Intravenous (not	280 Mg, Qow		Not Reported

Diarrhoea; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Short Stature; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User			otherwise specified)		
	Actemra	S	Intravenous (not otherwise specified)	280 Mg, Weekly	Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Qd	Not Reported
	Anakinra	S	Subcutaneous	Unk, 50	Not Reported
	Etanercept	S	Subcutaneous	25 Mg, Weekly	Not Reported
	Etanercept	S	Subcutaneous	12.5 Mg, Weekly	Not Reported
	Immunoglobulins [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
	Immunoglobulins [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
	Immunoglobulins [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg/Kg, Weekly	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg/M2	Not Reported
	Methotrexate	S	Unknown	Unk, Weekly	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	5 Mg, Bid	Not Reported
	Prednisone	S	Oral	3 Mg, Bid	Not Reported
	Prednisone	S	Unknown	1.3 Mg, Bid	Not Reported
	Sulfasalazine	S	Oral	250 Mg, Qd	Not Reported
	Sulfasalazine	S			Not Reported
	Triamcinolone	S	Unknown	Unk	Not Reported
	Triamcinolone	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Unk	Not Reported
	Enbrel	S	Subcutaneous	25 Mg, Weekly	Not Reported
	Tocilizumab	S	Unknown	250 Mg, Qd	Not Reported
	Tocilizumab	S	Intravenous (not	280 Mg Qcy (Every 2	Not Reported

			otherwise specified)	Weel)	
	Isoniazid;Rifampicin	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Folic Acid	C			Not Reported
	Triamcinolone Hexacetonide	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17614242	EXPEDITED (15-DAY)		HO, OT	BR-ADVANZ PHARMA-202003002062			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Arthropathy; Calculus Bladder; Cholecystectomy; Decreased Immune Responsiveness; Emotional Disorder; Gait Disturbance; Herpes Virus Infection; Herpes Zoster; Off Label Use	Hydroxychloroquine			S	Oral	1 Dosage Form, Qd Coated Tablet		Concordia
	Hydroxychloroquine			S	Oral	Coated Tablet1 Dosage Form, Qd		Concordia
	Aradois			C		50 Mg		Not Reported
	Influenza			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17678136	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-202004002834			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	1 Tablet Once A Day And 2 Tablets Once A Day, Alternately		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	1 Tablet Once A Day And 2 Tablets Once A Day, Alternately		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17699692	EXPEDITED (15-DAY)		LT, OT	CH-PFIZER INC-2020161844		86 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hypoglycaemia	Tazobac			S	Intravenous (not otherwise specified)	4.5 G, 3x/Day		Pfizer
	Tazobac			S	Intravenous (not otherwise specified)	2.5 G, Single		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	800 Mg, Single (In Total)		Not Reported
	Cymbalta			C	Oral	60 Mg, 1x/Day		Not Reported
	Nexium Mups [Esomeprazole Magnesium]			C	Oral	20 Mg, 1x/Day		Not Reported
	Calciparine			C	Subcutaneous	5000 Iu, 2x/Day		Not Reported
	Lantus			C	Subcutaneous	20 Iu		Not Reported
	Lantus			C	Subcutaneous	10 Iu, 1x/Day		Not Reported
	Prednisone			C	Oral	10 Mg, 1x/Day		Not Reported
	Pregabalin			C	Oral	25 Mg, 2x/Day		Not Reported
	Torasemide			C	Oral	5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17765723	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200500991		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

Orencia	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil /00072602/	S	Oral	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Naproxen	C	Unknown	Not Reported
Atorvastatin	C		Not Reported
Bisoprolol	C		Not Reported
Digoxin	C		Not Reported
Folic Acid	C		Not Reported
Furosemide	C		Not Reported
Hydrochlorothiazide	C		Not Reported
Methotrexate	C		Not Reported
Nifedipine	C		Not Reported
Palafer	C		Not Reported
Pantoprazole	C		Not Reported
Plaquenil /00072602/	C		Not Reported
Prednisone	C		Not Reported
Synthroid	C		Not Reported
Toloxin /00017701/	C		Not Reported
Valsartan	C		Not Reported
Vitamin D3	C		Not Reported
Xarelto	C		Not Reported
Xeljanz	C		Not Reported
Zinc Citrate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17769484	EXPEDITED (15-DAY)		DE, HO, OT	FR-MYLANLABS-2020M1046097			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Discomfort; Electrocardiogram Qt Prolonged; Intentional Product Misuse; Loss Of Consciousness; Off Label Use; Ventricular	Azithromycin			S	Unknown	Unk		Not Reported
	Plaquenil /00072603/			S	Unknown	Unk		Mylan

Arrhythmia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17778085	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200505937		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Adverse Event; Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Neck Pain; Neck Surgery; Off Label Use; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17806672	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200517490		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Sulfasalazine	S				Not Reported
Anakinra	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17806681	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200517483			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Synovitis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Xeljanz			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Leflunomide			S	Endocervical			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituxan			C				Not Reported
	Prednisone			C				Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17806682	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200517486			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Tofacitinib			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17812673	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200517494		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17812678	EXPEDITED (15-DAY)		DS, HO	CA-JNJFOC-20200517499		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Condition Aggravated; Drug Ineffective; Haematemesis; Hepatotoxicity; Joint Swelling; Nausea; Platelet Count Increased; Vitamin D Decreased; Vomiting	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Rosuvastatin			C	Unknown			Not Reported
	Betahistine			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Vitamin C /00008001/			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17817547	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201709-005382			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain;	Hydroxychloroquine			S	Oral	200 Mg, Bid		Concordia
	Arava			S	Oral	20 Mg		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Humira			S	Subcutaneous	20 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	Unk, Qd		Not Reported

Peripheral Swelling; Rheumatoid Arthritis	Methotrexate		S	Subcutaneous	20 Mg, Weekly	Not Reported
	Methotrexate		S	Subcutaneous	20 Mg	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Prednisone		S	Oral	1 Dosage Form, Qd	Not Reported
	Sulfasalazine		S	Unknown	1000 Mg, Bid	Not Reported
	Xeljanz		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17820785	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2020202410		40 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Acute; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, Daily		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, Daily		Not Reported
	Methylprednisolone			C		40-80 Mg, Daily		Not Reported
	Acetaminophen			C		1.2-1.8 G, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17831439	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2020-025875		77 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Injury; Pruritus; Purpura; Rash	Azithromycin			S	Oral	1 Dosage Form, Once A Day		Aurobindo
	Plaquenil			S	Oral	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17832244	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202005005639			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastroenteritis; Hepatitis; Nausea	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Concordia
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported

	Enbrel		C	Unknown	50 Mg, Weekly	Not Reported
	Humira		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17832458	EXPEDITED (15-DAY)		HO	CA-ROCHE-2603672		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Asthenia; Astigmatism; Balance Disorder; Blood Glucose Increased; Cataract; Dizziness; Fall; Fatigue; Feeling Hot; Gastric Disorder; Gastrointestinal Disorder; Head Discomfort; Headache; Hot Flush	Mycophenolate Mofetil			S	Unknown			Not Reported
	Belimumab			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported
	Gravol			C				Not Reported
	Neurontin			C				Not Reported
	Neurontin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17832699	EXPEDITED (15-DAY)		DS, OT	BE-ADVANZ PHARMA-202005005612			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Heart Rate Increased; Off Label Use; Vertigo	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Bid		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Folic Acid			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Levorichter 30			C		Unk		Not Reported
	Befact			C		Unk		Not Reported
	C-Will			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17832750	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005787			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Dupixent			S	Unknown	Unk		Not Reported
	Dupilumab Pre-Filled Syringe			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17832947	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-247719		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Exposure During Pregnancy; Foetal Death; Foetal Growth Restriction; Pre-Eclampsia	Hydroxychloroquine			S	Unknown	Unk		Sun
	Methyldopa			S	Unknown	Unk		Sun
	Nifedipine			S	Unknown	Unk		Sun
	Prednisone			S	Unknown	Unk		Mutual

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17833269	EXPEDITED (15-DAY)		OT	IL-TEVA-2020-IL-1242016		43 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia Areata; Drug Ineffective; Gastrointestinal Disorder; Retinal Injury	Methotrexate			S	Unknown	Up To Dose		Barr
	Hydroxychloroquine			S	Unknown			Teva
	Belimumab			S	Unknown			Not Reported
	Triamcinolone			S	Intradermal			Not Reported
	Prednisone			C	Unknown			Not Reported
	Azathioprine			C	Unknown	Up To Dose		Not Reported
	Warfarin			C	Unknown			Not Reported

	Aspirin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17833476	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201711-006533			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Kineret			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Anakinra			S	Unknown	100 Mg, Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Desoximetasone			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Prednisone			C				Not Reported
	Cortisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17833488	EXPEDITED (15-DAY)		DS	CA-ROCHE-2601407		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 365		Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Folic			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone			S	Oral			Not Reported
	Cortisone Acetate			S	Oral			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Desoximetasone			S	Cutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Oral			Not Reported
	Folic Acid			S	Oral			Not Reported

Fosamax	S	Oral		Not Reported
Golimumab	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Leflunomide	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Intra-arterial		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate Sodium	S	Oral	Therapy Duration: 11.0 Years	Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 11.0 Months	Not Reported
Paracetamol	S	Unknown		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral	Therapy Duration: 365	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfathalidine	S	Subcutaneous		Not Reported
	Sulfathalidine	S			Not Reported
	Topicort [Desoximetasone]	S	Oral		Not Reported
	Topicort [Desoximetasone]	S	Unknown		Not Reported
	Topicort [Desoximetasone]	S	Subcutaneous		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Acetaminophen	C			Not Reported
	Salazopyrin	C			Not Reported
	Tofacitinib Citrate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17833501	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605476			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Off Label Use; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Xeljanz	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17833562	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605159		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Pulmonary Mass	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Calcium Carbonate			C				Not Reported
	Cetirizine			C				Not Reported
	Cranberry [Vaccinium Spp.]			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Olopatadine			C				Not Reported
	Prednisone			C				Not Reported
	Quinapril Hydrochloride			C				Not Reported
	Sandoz Rabeprazole			C	Unknown			Not Reported
	Singulair			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17833589	EXPEDITED (15-DAY)		DE, OT	US-ADVANZ PHARMA-202005005717			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Off Label Use	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17833726	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US-001640			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Pre-Eclampsia	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Prednisone			S	Unknown	Unk		Not Reported
	Nifedipine			S	Unknown	Unk		Not Reported
	Methyldopa			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17833823	EXPEDITED (15-DAY)		HO	CA-ROCHE-2600694		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Actemra			S	Unknown	Therapy Duration 6.0 Years		Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Lyrica	S	Unknown	Not Reported
Certolizumab Pegol	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Prednisone	C		Not Reported
Piroxicam	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17833843	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601050			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Bone Disorder; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Off Label Use; Pain; Peripheral Swelling; Rash; Swelling; Tendon Disorder; Tenosynovitis;	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not			Not Reported

Treatment Failure; Urticaria				otherwise specified)	
	Methotrexate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Gold		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Codeine		S	Unknown	Not Reported
	Arava		S	Oral	Not Reported
	Penicillin G Sodium		S	Unknown	Not Reported
	Penicillin V Potassium		S	Unknown	Not Reported
	Rocuronium		S	Unknown	Not Reported
	Rocuronium Bromide		S	Unknown	Not Reported
	Sulfamethoxazole And Trimethoprim		S	Unknown	Not Reported
	Prednisone		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17833947	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202005005760			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiac Arrest; Diarrhoea; Electrocardiogram Qt Prolonged; Hypoglycaemia; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834028	EXPEDITED (15-DAY)		DE, OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US-			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction	Hydroxychloroquine			S	Transplacental	Unk		Ipca
	Prednisone			S	Transplacental	Unk		Not Reported
	Nifedipine			S	Transplacental	Unk		Not Reported
	Methyldopa			S	Transplacental	Unk		Not Reported
	Azathioprine			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834089	EXPEDITED (15-DAY)		DE	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-248216		26 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy	Azithromycin			S	Oral	500 Mg Dia		Sun
	Dexametasona (722a)			S	Intravenous (not otherwise specified)	20 Milligram, Daily		Not Reported
	Enoxaparina (2482a)			S	Subcutaneous	40 Milligram, Daily		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg ; In Total		Not Reported
	Dexketoprofeno (7312a)			S	Intravenous (not otherwise specified)	25 Milligram, Tid		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834116	EXPEDITED (15-DAY)		HO, OT	ES-SA-2020SA133267		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Off Label Use; Thrombocytopenia	Hydroxychloroquine			S	Oral	400 Mg Day		Sanofi

Hydroxychloroquine	S				Sanofi
Azithromycin	S	Oral	500 Mg Day		Not Reported
Enoxaparin Sodium	S	Subcutaneous	80 Mg, Every 12 Hours		Sanofi
Roactemra	S	Intravenous (not otherwise specified)	600 Mg, 24h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834159	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606952			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834691	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS		14 DAY	Female	USA

INC.-2020-02479

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia	Hydroxychloroquine			S	Transplacental	Unk		Lupin
	Tacrolimus			S	Transplacental	Unk		Not Reported
	Azathioprine			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834700	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608271			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Mobility Decreased; Osteomyelitis	Rituximab			S	Intravenous drip			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Hydrocortisone Valerate			C				Not Reported
	Hydromorphone Hydrochloride			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Lyderm [Fluocinonide]			C				Not Reported
	Naproxen			C				Not Reported
	Prednisone			C				Not Reported
	Sodium Aurothiomalate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834701	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201612-006568			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Malaise; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Walking Aid User	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil		S	Oral	400 Mg, Qd	Concordia
	Hydroxychloroquine		S	Unknown	400 Mg, Qd	Concordia
	Arava		S	Oral	20 Mg, Qd	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Xeljanz		S	Oral	5 Mg, Bid	Not Reported
	Sulfasalazine		S	Unknown	500 Mg, Bid	Not Reported
	Methotrexate Sodium		S	Subcutaneous	20 Mg, Weekly	Not Reported
	Prednisone		S	Unknown	Unk	Not Reported
	Prednisone		S	Unknown	5 Mg, Qd	Not Reported
	Rituxan		S	Unknown	Unk	Not Reported
	Rituxan		S	Unknown	Unk	Not Reported
	Infliximab		S	Oral	300 Mg, Qd	Not Reported
	Pantoloc		C		Unk	Not Reported
	Atorvastatin		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834702	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201710-005674			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Fatigue; Gait	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Bid		Concordia
	Hydroxychloroquine			S	Unknown	200 Mg, Bid, Tablet		Concordia
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Paracetamol			S	Unknown	325 Mg		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Weekly		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Somnolence; Visual Impairment	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	2000 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Apo-Acetaminophen	S	Unknown	Unk Unk, Prn	Not Reported
	Tylenol	S	Unknown		Not Reported
	Acetaminophen, Diphenhydramine Hydrochloride	S	Unknown	Unk	Not Reported
	Tylenol	C		Unk	Not Reported
	Codeine Phosphate	C			Not Reported
	Meloxicam	C		Unk	Not Reported
	Methotrexate	C		Unk	Not Reported
	Synthroid	C			Not Reported
	Celebrex	C		Unk	Not Reported
	Hydromorph	C			Not Reported
	Leflunomide	C		Unk	Not Reported
	Acetaminophen, Codeine Phosphate	C			Not Reported
	Hydromorphone Hcl	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834708	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201903-000662			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Ocular Hypertension	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qod		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia

Prednisolone	S	Unknown	Unknown		Not Reported
Prednisolone	C		6 Mg, Qd		Not Reported
Prednisolone	C		Unk		Not Reported
Prograf	C		Unk		Not Reported
Actonel	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834709	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201702-001198			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthritis; Condition Aggravated; Drug Ineffective; Hormone Level Abnormal; Immobile; Intentional Product Misuse; Loss Of Personal Independence In Daily Activities; Menopausal Symptoms; Menopause; Mobility Decreased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd		Concordia
	Hydroxychloroquine			S	Oral	Unk, Qd		Concordia
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Not Reported
	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	1 Dosage Form, Weekly (50)		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Mefenamic Acid			S		400 Mg, Bid		Not Reported
	Mefenamic Acid			S		2 Dosage Form, Qd		Not Reported

	Mefenamic Acid	S		2 Dosage Form, Qd	Not Reported
	Arava	S	Unknown	20 Mg, Qd	Not Reported
	Sulfasalazine	C		Unk	Not Reported
	Advil	C	Unknown	400 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834731	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201811-003897			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Application Site Pain; Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Physical Disability; Platelet Count Increased; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Treatment Failure; Vascular Access Complication; White Blood	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg/M2, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported
	Abatacept			S				Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Tocilizumab			S				Not Reported
	Etanercept			S	Unknown	15 Mg, Freq: Unk X 1 Weeks		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Weekly		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	420 Mg, Unk		Not Reported
	Infliximab			S	Unknown	200 Mg, Weekly		Not Reported

Cell Count Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834768	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605290			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Off Label Use; Oral Discomfort; Uveitis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Cimzia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835009	EXPEDITED (15-DAY)		OT	CA-ROCHE-2607444		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Psoriatic Arthropathy; Synovitis	Rituximab			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Apremilast	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Cimzia	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Otezla	S	Unknown	Not Reported
	Otezla	S	Oral	Not Reported
	Infliximab	C		Not Reported
	Benzylpenicillin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835046	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201702-001115			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthritis; Condition Aggravated; Drug Ineffective; Drug Ineffective; Drug Ineffective; Menopausal Symptoms; Musculoskeletal Stiffness; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd		Concordia
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Oral	10 Mg, Weekly		Not Reported
	Methotrexate			S	Oral	20 Mg, Weekly		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	1 Dosage Form, Unk		Not Reported
	Advil			S	Unknown	400 Mg, Bid		Not Reported

	Xeljanz	S	Unknown	Unk		Not Reported
	Xeljanz	S	Unknown	Unk		Not Reported
	Xeljanz	S	Unknown	5 Mg, Bid		Not Reported
	Mefenamic Acid	S		400 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835058	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602950			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835073	EXPEDITED (15-DAY)		OT	BR-PFIZER INC-2020204798		65 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Fibrin D Dimer Increased; Gastrointestinal Haemorrhage; Haematochezia; Off Label Use; Oxygen Saturation Decreased; Product Use In Unapproved Indication; Product Use Issue	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
	Reuquinol			S	Oral	400 Mg, 2x/Day		Not Reported
	Reuquinol			S	Oral	400 Mg, 1x/Day		Not Reported
	Oseltamivir [Oseltamivir Phosphate]			C		Unk Unk, 2x/Day		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Bromoprida			C	Intravenous (not otherwise specified)	10 Mg, 3x/Day		Not Reported
	Clexane			C	Subcutaneous	80 Mg, 2x/Day		Not Reported
	Amiodarone Hcl			C	Intravenous (not otherwise specified)	900 Mg, As Needed		Not Reported
	Dormire [Midazolam Hydrochloride]			C	Intravenous (not otherwise specified)	100 Mg, As Needed		Not Reported
	Fentanest [Fentanyl Citrate]			C	Intravenous (not otherwise specified)	2500 Ug, As Needed		Not Reported
	Noradrenaline [Norepinephrine]			C	Intravenous (not otherwise specified)	16 Mg, As Needed		Not Reported
	Lactulona			C	Oropharingeal	20 Ml, 3x/Day		Not Reported
	Lasix [Furosemide]			C	Intravenous (not otherwise specified)	20 Mg, As Needed		Not Reported
	Luftal Max			C	Oropharingeal	40 Drop, 3x/Day		Not Reported

	Nexium [Esomeprazole Magnesium]	C	Oropharingeal	20 Mg, 1x/Day	Not Reported
	Nujol	C	Oropharingeal	20 Ml, 3x/Day	Not Reported
	Zinforo	C	Intravenous (not otherwise specified)	600 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835077	EXPEDITED (15-DAY)		OT	ES-ACCORD-183570		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Gastrointestinal Pain; Off Label Use	Hydroxychloroquine			S	Oral			Not Reported
	Kaletra			S	Oral	Strength-200/50 Mg		Not Reported
	Omeprazole			C	Oral			Not Reported
	Paracetamol			C	Oral	Strength-1,000 Mg 40 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835078	EXPEDITED (15-DAY)		DE, OT	ES-ACCORD-183327		90 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gr		Not Reported
	Morphine			S	Intravenous (not otherwise specified)	Sedation		Not Reported
	Furosemide			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835083	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200528684			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Head	Remicade			S	Intravenous (not			Janssen

Injury; Road Traffic Accident				otherwise specified)	
	Actemra		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835088	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200528681			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lymphoma	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835134	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200528667			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen

Simponi	S	Subcutaneous	Janssen
Actemra	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Desoximetasone	S	Oral	Not Reported
Enbrel	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Fosamax	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Prednisone	S	Unknown	Not Reported
Reactine /00884302/	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835140	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020205698		34 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835335	EXPEDITED (15-DAY)		HO, OT	IT-ACCORD-183181		27 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19	Mycophenolic Acid			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisone/Prednisone Acetate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835346	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020208547		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	600 Mg, 1x/Day		Not Reported
	Rocephine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835384	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2020208562		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Off Label Use; Product Use In Unapproved Indication; Thrombocytopenia	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Enoxaparin			S	Subcutaneous	80 Mg, 2x/Day (Every 12 Hours)		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835454	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606654		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Pain; Peripheral Swelling; Rash; Swelling; Treatment Failure; Urticaria	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Codeine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rocuronium Bromide			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfamethoxazole/Trimethoprim			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835500	EXPEDITED (15-DAY)		HO	CA-ABBVIE-20K-028-3420872-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Symptom; Heart Rate Irregular; Malaise; Weight Decreased	Rinvoq			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835715	EXPEDITED (15-DAY)		HO, OT	CA-ADVANZ PHARMA-MAPI_00010560			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Leflunomide			S	Unknown	Unknown		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Kineret			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powderfor Solution Intravenous		Not Reported
	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Cellcept			S	Unknown	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Celebrex			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Humira			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835815	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201711-006254			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Unknown	200 Mg, Bid	Concordia
	Arava	S	Oral	20 Mg, Qd	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	50 Mg, Weekly	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Paracetamol	S	Unknown	Unk	Not Reported
	Paracetamol	S	Unknown	325 Mg, Tablet	Not Reported
	Meloxicam	C		Unk	Not Reported
	Methotrexate	C		25 Mg/Ml	Not Reported
	Synthroid	C		Unk	Not Reported
	Tylenol	C			Not Reported
	Acetaminophen And Codeine Phosphate	C			Not Reported
	Leflunomide	C		Unk	Not Reported
	Celebrex	C		Unk	Not Reported
	Hydromorphone Hcl	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17836106	NON-EXPEDITED			US-PFIZER INC-2020207847		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Azithromycin			S		Unk		Pfizer
	Hydroxychloroquine Sulfate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17836374	EXPEDITED (15-DAY)		HO, OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2020VAL000409			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Off Label Use; Ventricular Fibrillation	Furosemide			S	Oral	Unk		Validus
	Plaquenil /00072603/			S	Oral	Unk		Not Reported
	Plaquenil /00072603/			S				Not Reported
	Risordan /07346501/			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Irbesartan			S	Oral	Unk		Not Reported
	Carvedilol			S	Oral	Unk		Not Reported
	Azithromycin			S	Oral	250 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17836411	EXPEDITED (15-DAY)		HO	CA-JNJFOC-20200532831		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Myochrysine			S	Subcutaneous	Also Reported As		Not Reported

Daily Activities; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Orencia		S	Unknown	Intramuscular	Not Reported
	Rituximab		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Ciclosporin		C	Unknown		Not Reported
	Prednisone		C	Unknown		Not Reported
	Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17837105	EXPEDITED (15-DAY)		DE, OT	ES-MYLANLABS-2020M1051992		86 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depressed Mood; Hypertransaminasaemia; Long Qt Syndrome	Azithromycin			S		Unk		Not Reported
	Hidroxicloroquina /00072601/			S		Unk		Mylan
	Kaletra			S	Unknown	Unk		Mylan
	Metilprednisolona /00049601/			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17837148	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020208538		90 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported
	Tavanic			S	Oral	1000 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17837487	EXPEDITED (15-DAY)		HO	CA-JNJFOC-20200526760		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Alendronic Acid	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	11290381	EXPEDITED (15-DAY)		OT	CA-ROCHE-1610671		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 5 Years		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 3 Years, Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 3 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 1 Year		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown	Therapy Duration: 9 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 1 Year		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 1 Year		Not Reported
	Arava			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	11.0 Years		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Vaginal			Not Reported
	Methotrexate			S	Unknown			Not Reported

Ativan	C	Unknown		Not Reported
Cortisone	C	Intramuscular		Not Reported
Cortisone	C	Intra-articular		Not Reported
Cortisone	C	Oral		Not Reported
Darifenacin	C	Unknown	As Required	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	As Required	Not Reported
Furosemide	C	Unknown		Not Reported
Loperamide	C	Unknown		Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown		Not Reported
Omnaris	C	Unknown	Spray, Metered Dose	Not Reported
Pantoprazole Sodium	C			Not Reported
Synthroid	C			Not Reported
Vagifem	C	Unknown	Vaginal Tablet	Not Reported
Anakinra	C			Not Reported
Abatacept	C			Not Reported
Leflunomide	C	Unknown		Not Reported
Lasix [Furosemide]	C	Unknown		Not Reported
Dyclonine Hydrochloride	C			Not Reported
Enablex [Darifenacin Hydrobromide]	C	Unknown	Tablet (Extended Release)	Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Tablet (Enteric Coated)	Not Reported
Urispas	C	Unknown		Not Reported
Triamcinolone Acetonide	C	Intra-articular		Not Reported
Trimethoprim	C	Unknown		Not Reported
Restasis	C	Unknown		Not Reported
Plantago Ovata	C	Unknown		Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown		Not Reported
Pantoprazole	C			Not Reported
Oxyneo	C	Unknown		Not Reported
Orphenadrine Hydrochloride	C	Unknown	1.0 Dosage Forms	Not Reported
Morphine Sulfate	C	Unknown		Not Reported

	Kenalog [Triamcinolone Acetonide]	C	Intra-articular	Not Reported
	Kineret	C	Unknown	Not Reported
	Kadian	C	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported
	Dyclone	C		Not Reported
	Desoximetasone	C	Oral	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Desoximetasone	C	Intramuscular	Not Reported
	Diphenhydramine	C		Not Reported
	Darifenacin Hydrobromide	C	Unknown	Not Reported
	Codeine	C		Not Reported
	Acetaminophen	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	11379748	EXPEDITED (15-DAY)		OT	CA-ROCHE-1620025		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Back Disorder; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Mouth Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Synovitis; Treatment	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 1 Year		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

Failure; Vasculitic Rash	Methotrexate	S	Subcutaneous	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Hydromorph Contin	C		Not Reported
	Dilaudid	C		Not Reported
	Amlodipine	C		Not Reported
	Eletriptan	C		Not Reported
	Cimzia	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	12082828	EXPEDITED (15-DAY)		OT	CA-ROCHE-1712228			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)	4-8mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral	Adequate Trial Of 3months In 2010		Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 195 Days Form Of Admin Text: Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	Therapy Duration: 6 Years		Not Reported
	Methotrexate			S	Intramuscular	Therapy Duration: 6 Years		Not Reported
	Orencia			S	Intravenous (not			Not Reported

		otherwise specified)		
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Therapy Duration: 6 Years	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
Apo-Hydroxyquine	S	Oral		Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Leflunomide	S	Oral		Not Reported
Naproxen Sodium	S	Unknown		Not Reported
Naproxen Sodium	S	Unknown		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Acetylsalicylic Acid	C	Unknown		Not Reported
Asa	C	Unknown		Not Reported
Asa	C	Unknown		Not Reported
Lantus	C	Subcutaneous	Solution	Not Reported
Lozide [Indapamide]	C			Not Reported
Prednisone	C			Not Reported
Ramipril	C			Not Reported
Ergocalciferol	C			Not Reported
Vitamin D3	C			Not Reported
Xeljanz	C	Oral		Not Reported
Calcium	C			Not Reported
Metformin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	13251082	EXPEDITED (15-DAY)		OT	CA-ROCHE-1895049		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain;	Actemra			S	Unknown			Not Reported

Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Arava	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Therapy Duration: 4.0 Month(S)	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Winpred	S	Oral		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	13266498	EXPEDITED (15-DAY)		OT	CA-BAXTER-2017BAX007297		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Metronidazole Injection, Usp			S	Unknown	Dosage Form: Not Specified		Baxter
	Metronidazole Injection, Usp			S	Intravenous (not otherwise specified)	Dosage Form: Liquid Intravenous		Baxter
	Arava			S	Unknown	Tablet		Not Reported
	Arthrotec			S	Unknown			Not Reported
	Bisoprolol			S	Unknown	Dosage Form: Tablet		Not Reported
	Bisoprolol Fumarate			S	Unknown	Tablet		Not Reported

Ceclor	S	Unknown	Dosage Form Not Specified	Not Reported
Celebrex	S	Oral		Not Reported
Celebrex	S	Oral	Dosage Form: Capsules	Not Reported
Demerol	S	Unknown	Dosage Form Not Specified	Not Reported
Erythromycin Estolate	S	Unknown	Dosage Form Not Specified	Not Reported
Erythromycin	S	Unknown	Dosage Form Not Specified	Not Reported
Humira	S	Unknown	Solution Subcutaneous	Not Reported
Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
Leflunomide	S	Unknown		Not Reported
Levofloxacin	S	Unknown	Dosage Form Not Specified	Not Reported
Levofloxacin	S	Unknown		Not Reported
Lyrica	S	Unknown		Not Reported
Meperidine Hydrochloride	S	Unknown		Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Norfloxacin	S	Unknown	Dosage Form Not Specified	Not Reported
Plaquenil	S	Unknown	Tablet	Not Reported
Plaquenil	S	Oral	Tablet	Not Reported
Prednisone	S	Unknown	Dosage Form Not Specified	Not Reported
Sulfasalazine	S	Unknown	Dosage Form Not Specified	Not Reported
Erythro Base	S	Unknown	Dosage Form: Tablet	Not Reported
Methotrexate	S	Unknown	Dosage Form: Not Specified	Not Reported
Levofloxacin Hemihydrate	S	Unknown		Not Reported
Cefaclor	S	Unknown		Not Reported

	Pregabalin	S	Unknown		Not Reported
	Celecoxib	S	Oral	200 Mg, Qd	Not Reported
	Meperidine	S	Unknown	Dosage Form: Not Specified	Not Reported
	Apo-Leflunomide	S	Unknown	Dosage Form: Tablet	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	13266763	EXPEDITED (15-DAY)		OT	CA-ROCHE-1897125			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Decreased Appetite; Drug Ineffective; Drug Intolerance; Feeding Disorder; Feeding Disorder; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Stomatitis; Weight Decreased	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Champix			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Valacyclovir [Valaciclovir]			C				Not Reported
	Vimovo			C				Not Reported
	Crestor			C				Not Reported
	Oxycocet			C	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	13947306	EXPEDITED (15-DAY)		OT	CA-ROCHE-1875144		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Off Label Use; Photosensitivity Reaction; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Stomatitis; Urticaria	Actemra			S	Unknown			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Marijuana			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cannabis Sativa			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Oxycodone Hydrochloride			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	14299394	EXPEDITED (15-DAY)		OT	CA-ROCHE-2038238			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Arthropathy;	Actemra			S	Unknown	Therapy Duration: 5 Years		Not Reported
	Rituxan			S	Intravenous (not			Not Reported

Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete			otherwise specified)		
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Therapy Duration: 6 Months	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Leflunomide	S	Unknown	Therapy Duration: 2 Years	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Therapy Duration: 790 Nos	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown	Therapy Duration: 3 Years	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 8 Months	Not Reported
	Anakinra	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Oral		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine Sulphate	S	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Wellbutrin	C	Oral	Extended Release	Not Reported
	Xeljanz	C	Unknown		Not Reported
	Bupropion	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	14549482	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP006555			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Arthritis; Chest Pain; Drug Ineffective; Fibromyalgia; Hla Marker Study Positive; Immunodeficiency; Kyphoscoliosis; Musculoskeletal Discomfort; Musculoskeletal Stiffness; Myofascial Pain Syndrome; Plantar Fasciitis; Somnolence; Spinal Osteoarthritis; Therapeutic Product Effect Incomplete	Amitriptyline			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Meloxicam			S	Unknown	Unk		Apotex
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Mobicox			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	500 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	14815519	EXPEDITED (15-DAY)		OT	CA-ROCHE-2110721			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Contraindicated Product Administered; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use;	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 4.0 Year(S)		Not Reported

Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Treatment Failure; Weight Decreased	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown	Therapy Duration: 4.0 Year(S)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 2.0 Year(S) Powder For Solution Intravenous	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Imuran [Azathioprine]	S	Unknown		Not Reported
	Certolizumab Pegol	S	Unknown	Therapy Duration: 9.0 Month(S)	Not Reported
	Gold	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Lyrica	S	Unknown		Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous		Not Reported
	Varicella Zoster Vaccine Live	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	15454776	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190744		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Asa			C	Unknown			Not Reported
	Clonazepam			C	Oral			Not Reported
	Desipramine			C	Unknown			Not Reported
	Gabapentin			C	Oral			Not Reported
	Nitroglycerin			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	15612498	EXPEDITED (15-DAY)		OT	PHHY2018ES109862		22 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Oesophageal Candidiasis; Off Label Use; Opportunistic Infection; Product Use In Unapproved Indication	Prednisone			S	Unknown	60 Mg, Qd		Not Reported
	Prednisone			S	Unknown	2.70 G, Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Novartis
	Hydroxychloroquine			S				Novartis
	Imurel			S	Unknown	Unknown Dose		Not Reported

	Imurel	S				Not Reported
	Imurel	S				Not Reported
	Azathioprine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	15633947	EXPEDITED (15-DAY)		HO, OT	PHHY2018IT156440		15 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bronchitis; Chills; Cushingoid; Drug Ineffective; Gastrointestinal Disorder; Haematuria; Headache; Hypertransaminasaemia; Lupus Nephritis; Meningitis Cryptococcal; Muscle Atrophy; Muscle Hypertrophy; Nausea; Off Label Use; Pneumonia; Proteinuria; Pyrexia	Hydroxychloroquine			S	Oral	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Mycophenolate Mofetil			S	Unknown	1 G, Qd		Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Prednisone			S	Oral	1 Mg/Kg, Qd		Not Reported
	Prednisone			S				Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	350 Mg, Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	375 Mg/M2, Unk		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported
	Cyclophosphamide			S	Oral	1 Mg/Kg, Unk		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	300 Unk, 1x Pulse		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	500 Mg 1x Pulse Therapy		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	15734887	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1091973			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia	Azathioprine			S	Transplacental			Not Reported

	Hydroxychloroquine	S	Transplacental		Not Reported
	Prednisone	S	Transplacental		Not Reported
	Tacrolimus	S	Transplacental		Not Reported
	Betamethasone	S	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	16257921	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-039626		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Back Disorder; Drug Ineffective; Drug Intolerance; Mouth Ulceration; Vasculitic Rash	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Q4wk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Anakinra			S	Unknown	100 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Leflunomide			S	Oral	20 Milligram, Q2wk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram, Qd		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	16697274	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2019344315			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain	Ramipril			S	Oral	1 Df, Bid (1 - 0 - 1)		Pfizer
	Ramipril			S	Unknown	5 Mg, Qd		Pfizer
	Apixaban			S	Unknown	2.5 Mg, Bid		Pfizer

In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Apixaban	S	Unknown	2 Df, Qd	Pfizer
	Lyrica	S	Unknown	100 Mg, Tid	Pfizer
	Lyrica	S	Unknown	1 Df, Tid (1 Df, 3x/Day (1 - 1- 1))	Pfizer
	Pregabalin	S	Unknown	100 Mg, Tid	Pfizer
	Pregabalin	S	Unknown	1 Df, 3x/Day	Pfizer
	Omeprazole	S	Oral	1 Df, Bid (1 - 0 - 1)	Pfizer
	Omeprazole	S	Oral	20 Mg, Bid (40mg/Day)	Pfizer
	Sildenafil Citrate	S	Unknown	60 Mg, Qd	Pfizer
	Quensyl	S	Unknown	40 Mg, Bid (80mg/Day)	Not Reported
	Quensyl	S	Unknown	20 Mg, Bid (40 Mg/Day)	Not Reported
	Volibris	S	Oral	30 Mg, Qd	Not Reported
	Volibris	S	Oral	1 Df, Qd	Not Reported
	Spasmolyt	S	Unknown	1 Df, Qd	Not Reported
	Spasmolyt	S	Unknown	30 Mg, Qd	Not Reported
	Spasmolyt	S	Unknown	30 Mg, Qd	Not Reported
	Spasmolyt	S	Unknown	15 Mg, Qd	Not Reported
	Roactemra	S	Subcutaneous	162 Mg, Qw (Solution For Injection In Pre-Filled Syringe)	Not Reported
	Roactemra	S	Subcutaneous	162 Mg, Qw	Not Reported
	Ambrisentan	S	Unknown	30 Mg, Qd	Not Reported
	Ambrisentan	S	Oral	1 Df, Qd	Not Reported
	Ambrisentan	S		Unk	Not Reported
	Ambrisentan	S	Unknown	30 Mg, Qd	Not Reported
	Ambrisentan	S	Unknown	30 Mg, Qd	Not Reported
	Ambrisentan	S	Oral	1 Df, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	16872434	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2412613		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency;	Actemra			S	Subcutaneous			Not Reported
Ankle Arthroplasty; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthritis;	Rituxan			S	Intravenous (not otherwise specified)	Cyclical		Not Reported
Arthropathy; Condition Aggravated;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
Contraindicated Product Administered; Diarrhoea;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Intolerance; Foot Deformity; Foot Operation;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Gastroenteritis Viral; Hand Deformity; Hypertension;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Hypocalcaemia; Hypokalaemia; Hypotension; Ill-Defined	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Disorder; Immunodeficiency;	Rituxan			S	Subcutaneous			Not Reported
Infection; Intentional	Actemra			S	Unknown			Not Reported
Product Use Issue; Joint Destruction; Limb	Anakinra			S	Subcutaneous			Not Reported
Discomfort; Loss Of Consciousness; Loss Of Personal Independence In	Anakinra			S	Subcutaneous			Not Reported
Daily Activities; Malaise;	Anakinra			S	Subcutaneous			Not Reported
Mobility Decreased; Nausea; Nodule; Obesity;	Anakinra			S	Subcutaneous			Not Reported
Off Label Use; Pleural Effusion; Polyarthritis;	Anakinra			S	Subcutaneous			Not Reported
Psoriasis; Pulmonary Fibrosis; Pyrexia; Red	Arava			S	Oral			Not Reported
Blood Cell Sedimentation Rate Abnormal;	Arava			S	Unknown			Not Reported
Rheumatoid Arthritis;	Cimzia			S	Subcutaneous			Not Reported
Rheumatoid Factor Positive; Septic Shock;	Cimzia			S	Subcutaneous			Not Reported
Synovitis; Therapeutic Product Effect Decreased;	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Therapy Non-Responder; Vomiting; Wheelchair User	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Actonel	S	Oral	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported

Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Leflunomide	S	Oral	Not Reported
Leflunomide	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Apo-Naproxen	S	Unknown	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Gammagard	S	Intravenous (not otherwise specified)	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Naproxen	S	Unknown	Not Reported

	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Unknown	Not Reported
	Triamcinolone Acetonide	S	Unknown	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Not Reported
	Sodium Aurothiomalate	S	Subcutaneous	Not Reported
	Risedronate Sodium	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Folic Acid	C		Not Reported
	Risedronate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	16927061	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-096726		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Pressure Fluctuation; Body Height Decreased; Drug Ineffective; Drug Intolerance; Flushing; Inflammation; Intentional Product Use Issue; Interstitial Lung Disease; Irritable Bowel Syndrome; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Lyrica			S	Unknown	150 Milligram		Not Reported
	Sulfasalazin			S	Unknown	1000 Milligram, Bid		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	400 Milligram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not	1000 Milligram		Not Reported

			otherwise specified)		
	Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	3000 Milligram, Qd	Not Reported
	Esomeprazole	C	Unknown	40 Milligram, Qd	Not Reported
	Esomeprazole Sodium	C	Unknown	Unk	Not Reported
	Bimatoprost	C	Ophthalmic	Unk Unk, Qd	Not Reported
	Pseudoephedrine Hydrochloride	C	Unknown	10 Milligram, Qd	Not Reported
	Trazodone	C	Unknown	200 Milligram, Qd	Not Reported
	Valsartan	C	Unknown	Unk, Qd	Not Reported
	Wellbutrin	C	Unknown	300 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	16931807	EXPEDITED (15-DAY)		OT	CA-ROCHE-2435261			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Mobicox			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17245909	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512661		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchitis; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Off Label Use; Pneumonia; Product Dose Omission; Skin Reaction; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Thyroid Disorder; Treatment Failure; Vomiting	Actemra			S	Unknown	1.0 Dosage Forms		Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Cimzia			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Baclofen			C	Unknown			Not Reported
	Baclofen			C				Not Reported
	Calcium			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown	1.0 Dosage Forms		Not Reported
	Estradiol			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Gravol			C	Unknown			Not Reported

	Levaquin	C	Unknown	Not Reported
	Levaquin	C		Not Reported
	Morphine	C	Unknown	Not Reported
	Zingiber Officinale	C	Unknown	Not Reported
	Potassium Chloride	C	Unknown	Not Reported
	Valsartan	C	Unknown	Not Reported
	Xalatan	C	Ophthalmic	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17281970	EXPEDITED (15-DAY)		OT	CA-ROCHE-2521190			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diarrhoea; Drug Ineffective; Fibromyalgia; Gastrooesophageal Reflux Disease; Ill-Defined Disorder; Pain; Skin Irritation; Weight Increased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17299293	EXPEDITED (15-DAY)		OT	CA-ROCHE-2525016		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness;	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Gold	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Mobicox	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Depomedrol	C	Other			Not Reported
	Depomedrol	C	Other	Suspension Intraarticular		Not Reported
	Diclofenac	C	Unknown			Not Reported
	Pantoprazole Magnesium	C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17376739	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533781		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder; Therapy Partial Responder	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Actonel	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17390927	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540924			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Off Label Use; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17391235	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536677		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Off Label Use; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Codeine			S				Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 5.0 Years		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 9.0 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 15.0 Years		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Sulfasalazine	S	Unknown			Not Reported
Adalimumab	C	Unknown	Therapy Duration: 9.0 Years		Not Reported
Prednisone	C	Unknown	Therapy Duration: 9.0 Years		Not Reported
Prednisone	C	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17399182	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540688			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17464240	EXPEDITED (15-DAY)		HO	CA-ROCHE-2553935			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Nausea; Product Label Confusion; Treatment Failure; Vomiting	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Cimzia	C		Not Reported
	Enbrel	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17472233	EXPEDITED (15-DAY)		HO	CA-ROCHE-2556500		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tacrolimus			S	Unknown	6.0 Dosage Forms		Not Reported
	Tacrolimus			S	Unknown	5.0 Dosage Forms		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17558716	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567123		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Off Label Use; Red Blood Cell Sedimentation Rate Increased; Urticaria	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Usp		Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			C				Not Reported
	Ciclosporin			C				Not Reported
	Minocycline			C				Not Reported
	Penicillamine			C				Not Reported
	Prednisone			C				Not Reported
	Actemra			C	Unknown			Not Reported
	Phenylbutazone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17580222	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA1336			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Event; Contraindicated Product Administered; Drug Ineffective; Off Label Use	Kineret	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17614339	EXPEDITED (15-DAY)		DS	CA-ROCHE-2572169		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug Ineffective; Fine Motor Skill Dysfunction; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Musculoskeletal Disorder; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Therapeutic Product Effect Decreased; Treatment Noncompliance	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17722293	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1227376		74 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Off Label Use; Sinus Bradycardia	Azitromicina Teva 500 Mg Compresse Rivestite Con Film			S	Oral	500 Mg		Not Reported
	Plaquenil			S	Oral	400 Mg		Not Reported
	Stilnox 10 Mg Compresse Rivestite Con Film			C	Oral	10 Mg		Not Reported
	Clexane T			C	Subcutaneous	8000 Ku		Not Reported
	Lansoprazolo Teva Italia 30 Mg Capsule Rigide Gastroresistenti			C	Oral	30 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17722977	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589713			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Neutropenia; Off Label Use; Osteoarthritis; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Therapy Partial Responder; Urinary Tract Infection	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			C	Subcutaneous			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17729388	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200437131			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Remicade		S	Intravenous (not otherwise specified)	Janssen
	Actemra		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Celecoxib		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Orencia		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Prednisone		S	Unknown	Not Reported
	Celebrex		S		Not Reported
	Hydroxychloroquine Sulfate		S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17744167	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200436843		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Alopecia; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug Ineffective; Drug Intolerance; Lymphoma; Nausea; Neoplasm Malignant; Neutropenia; Onychoclasis; Osteoarthritis; Synovitis; Tachycardia; Tooth Loss; Type 2 Diabetes Mellitus; White Blood Cell Count Decreased	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Varicella Zoster Vaccine Live	S	Intravenous (not otherwise specified)	Not Reported
	Desoximetasone	C	Oral	Not Reported
	Diclofenac	C		Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17744168	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436826			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Rheumatoid Arthritis; Sciatica	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Caffeine			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Dorzolamide Hydrochloride			C				Not Reported
	Folic Acid			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported

	Meprobamate	C	Unknown	Not Reported
	Phosphate /01053101/	C		Not Reported
	Prednisone	C	Unknown	Not Reported
	Ramipril	C	Unknown	Not Reported
	Timolol Maleate	C	Ophthalmic	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17757965	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200500978		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Rheumatoid Arthritis; Synovitis; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17763317	EXPEDITED (15-DAY)		HO	CA-ROCHE-2594978		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy;	Rituxan			S	Intravenous (not			Not Reported

Asthenia; Condition Aggravated; Cough; Drug Ineffective; Fatigue; Fine Motor Skill Dysfunction; Goitre; Headache; Inflammation; Joint Swelling; Knee Arthroplasty; Lower Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Thyroid Disorder			otherwise specified)	
	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Celexa [Citalopram Hydrobromide]	C	Unknown	Not Reported
	Ketoprofen	C	Unknown	Not Reported
	Losec [Omeprazole]	C		Not Reported
	Naprosyn [Naproxen]	C		Not Reported
	Rosuvastatin Calcium	C		Not Reported
	Xeljanz	C	Oral	Not Reported
	Crestor	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17763565	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1231867		76 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Erythema; Off	Azitromicina Teva Italia (Azithromycin)			S	Oral	500 Mg		Not Reported

Label Use; Rash Pustular	Darunavir	S	Oral	800 Mg	Teva
	Ritonavir Sandoz	S	Oral	100 Mg	Not Reported
	Norvasc 5 Mg Compresse	S	Oral	10 Mg	Not Reported
	Clexane T	S	Subcutaneous	6000 Ku	Not Reported
	Plaquenil	S	Oral	400 Mg	Not Reported
	Eutirox	C			Not Reported
	Folifill	C			Not Reported
	Ceftriaxone Mylan Generics 2000 Mg Polvere Per Soluzione Per Infusione	C	Oral	1 Df	Not Reported
	Lasix Fiale	C			Not Reported
	Urbason Solubile	C	Intravenous (not otherwise specified)	1 Df	Not Reported
	Omeprazole	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17794557	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-024373		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Ventricular Fibrillation	Carvedilol			S	Oral	Unk		Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported
	Irbesartan Eg			S	Oral	Unk		Not Reported
	Lasilix			S	Oral	Unk		Not Reported
	Azithromycin Pfizer			S	Oral	250 Milligram, Once A Day		Not Reported
	Risordan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17806674	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200517468			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Remicade			S	Intravenous (not otherwise specified)			Janssen

Remicade	S	Intravenous (not otherwise specified)	Janssen
Remicade	S	Intravenous (not otherwise specified)	Janssen
Remicade	S	Intravenous (not otherwise specified)	Janssen
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine /00072603/	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Intramuscular	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Intramuscular	Not Reported

Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Intramuscular		Not Reported
Methotrexate	S	Unknown		Not Reported
Plaquenil /00072602/	S	Oral		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17806724	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200517462		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Cyclical		Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17812669	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200517507		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Cyst; Bone Erosion; Drug Ineffective; Hypertension; Therapeutic Response Decreased	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17813033	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200514296			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen

	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Simponi	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17815304	EXPEDITED (15-DAY)		DE, HO	GR-BIOVITRUM-2020GR2165		51 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Shock	Anakinra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S				Not Reported
	Meropenem			S				Not Reported
	Azithromycin			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Teicoplanin			S				Not Reported
	Hydrocortisone			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17815320	EXPEDITED (15-DAY)		DE, HO, OT	GR-BIOVITRUM-2020GR2200		74 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatomegaly; Hypoxia; Inflammatory Marker Increased; Off Label Use; Pyrexia; Shock; Splenomegaly	Anakinra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S				Not Reported
	Meropenem			S				Not Reported
	Azithromycin			S				Not Reported

	Hydroxychloroquine	S			Not Reported
	Teicoplanin	S			Not Reported
	Hydrocortisone	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17815343	EXPEDITED (15-DAY)		DE, OT	GR-BIOVITRUM-2020GR2202		84 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anuria; Off Label Use; Shock; Splenomegaly	Anakinra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S				Not Reported
	Meropenem			S				Not Reported
	Azithromycin			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Teicoplanin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17816644	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200514298			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17824697	EXPEDITED (15-DAY)		HO	CA-ROCHE-2600447		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abscess; Adrenal Insufficiency; Alanine Aminotransferase Increased; Ascites; Asthenia; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Potassium Decreased; Blood Pressure Diastolic Abnormal; Blood Pressure Increased; Congestive Hepatopathy; Depression; Diverticulitis; Endometrial Disorder; Enterococcus Test Positive; Fibrosis; Gamma-Glutamyltransferase Increased; Gastrointestinal Disorder; Generalised Oedema; Heart Rate Increased; Herpes Zoster; Hypersensitivity; Hypoglycaemia; Hypotension; Increased Appetite; Influenza; Infusion Related Reaction; Injection Site Extravasation; Intensive Care Unit Acquired Weakness; Intervertebral Disc Protrusion; Joint Effusion; Joint Swelling; Micturition Disorder; Myelopathy; Myopathy; Nasopharyngitis; Nausea;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Ceftazidime			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Piperacillin/Tazobactam			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rosuvastatin Calcium			S	Unknown			Not Reported
	Vancomycin Hydrochloride			S	Unknown			Not Reported
	Rosuvastatin			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Actonel			C	Unknown			Not Reported
	Apo Amlo			C				Not Reported
	Apo-K			C				Not Reported
	Diphenhydramine Hydrochloride			C	Oral			Not Reported
	Epoetin Alfa			C				Not Reported
	Escitalopram			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Hydroxychloroquine			C				Not Reported
	Januvia			C	Unknown			Not Reported

Nerve Compression; Neuropathy Peripheral; Neutropenia; Osteoarthritis; Pancytopenia; Peripheral Sensorimotor Neuropathy; Peritonitis; Pneumonia; Pseudomonal Bacteraemia; Rheumatoid Arthritis; Septic Shock; Therapeutic Response Decreased; Vomiting; Weight Decreased; Weight Increased	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
	Metoprolol	C		Not Reported
	Pantoloc [Pantoprazole]	C	Unknown	Not Reported
	Risedronate	C	Unknown	Not Reported
	Slow-K	C		Not Reported
	Tylenol	C		Not Reported
	Ventolin [Salbutamol Sulfate]	C		Not Reported
	Humalog	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17825815	EXPEDITED (15-DAY)		OT	BR-PFIZER INC-2020204791		72 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Pyrexia	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
	Reuquinol			S	Oral	400 Mg, 1x/Day		Not Reported
	Ceftriaxona [Ceftriaxone]			C	Intravenous (not otherwise specified)	2 G, 1x/Day		Not Reported
	Clexane			C	Subcutaneous	40 Mg, 1x/Day		Not Reported
	Euthyrox			C	Oral	37.5 Mg, 1x/Day		Not Reported
	Lorazepam			C	Oral	2 Mg, 1x/Day		Not Reported
	Nexium [Esomeprazole Magnesium]			C	Oral	20 Mg, 2x/Day (Every 12 Hours)		Not Reported
	Novalgina			C	Intravenous (not otherwise specified)	1 G, Every 6 Hours As Needed		Not Reported
	Meclin			C	Oral	50 Mg, 2x/Day		Not Reported
	Puran T4			C		37.5 Ug, 1x/Day		Not Reported
	Domperidone			C		10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17825820	EXPEDITED (15-DAY)		DE, OT	BR-PFIZER INC-2020204785		62 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Electrocardiogram Qt Prolonged; Off Label Use; Potentiating Drug Interaction; Product Use In Unapproved Indication; Pyrexia	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
	Reuquinol			S	Oral	400 Mg, 2x/Day 12/12h		Not Reported
	Reuquinol			S		400 Mg, 1x/Day		Not Reported
	Reuquinol			S		200 Mg, 1x/Day		Not Reported
	Atorvastatin Calcium			C		10 Mg, 1x/Day		Not Reported
	Oseltamivir			C	Oral	75 Mg, 2x/Day		Not Reported
	Zinforo			C	Intravenous (not otherwise specified)	600 Mg, 2x/Day		Not Reported
	Zinforo			C	Intravenous (not otherwise specified)	400 Mg, 2x/Day		Not Reported
	Zinforo			C	Intravenous (not otherwise specified)	600 Mg, 2x/Day		Not Reported
	Meronem			C	Intravenous (not otherwise specified)	1 G, 3x/Day 8 / 8h		Not Reported
	Linezolid			C	Intravenous (not otherwise specified)	600 Mg, 2x/Day		Not Reported
	Sodium Bicarbonate			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Bromoprida			C	Intravenous (not otherwise specified)	10 Mg, 3x/Day		Not Reported
	Potassium Chloride			C		Unk		Not Reported
	Sodium Chloride			C		Unk		Not Reported
	Dormire [Midazolam Hydrochloride]			C	Intravenous (not otherwise specified)	100 Mg, As Needed (As Physician Criteria)		Not Reported
	Fentanest [Fentanyl Citrate]			C	Intravenous (not otherwise specified)	2500 Ug, As Needed (As Physician Criteria)		Not Reported
	Hemofol			C	Subcutaneous	5000 Iu, 3x/Day		Not Reported

	Hepamax S	C	Unk	Not Reported
	Nexium [Esomeprazole Magnesium]	C	20 Mg, 1x/Day	Not Reported
	Aradois	C	50 Mg, 1x/Day	Not Reported
	Somalgin	C	81 Mg, 1x/Day	Not Reported
	Exodus [Escitalopram Oxalate]	C	10 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17830178	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1239952		40 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Hypertransaminasaemia	Hidroxicloroquina (2143a)			S	Oral	400 Mg W / 12 Hours Followed By 200 Mg W / 12 Hours. 1 Dosage Forms		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Azitromicina (7019a)			S	Unknown	Not Specified		Not Reported
	Ceftriaxona (501a)			S	Unknown	Not Specified		Not Reported
	Lopinavir/Ritonavir Accord 200 Mg/ 50 Mg Comprimidos Recubiertos Con P			S	Oral	400 Mg C / 12 Drops.2 Dosage Forms		Not Reported
	Lopinavir/Ritonavir Accord 200 Mg/ 50 Mg Comprimidos Recubiertos Con P			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17830292	EXPEDITED (15-DAY)		OT	NVSC2020FR145080		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Dysphagia; Muscle Disorder; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	400 Mg, Qd, 7.4 Mg/Kg/Day)		Novartis
	Chloroquine			S	Unknown	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17836250	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-026603		64 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypofibrinogenaemia	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Two Times A Day		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Gram, Once A Day		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17836482	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602499		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Ciclosporin			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Neoral	S	Oral		Not Reported
Neoral	S	Subcutaneous		Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Subcutaneous		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17836705	EXPEDITED (15-DAY)		HO	CA-ROCHE-2602962		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Off Label Use; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17836720	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605662		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Musculoskeletal Pain; Pain In Extremity; Pancreatic Carcinoma; Peripheral Swelling; Rheumatoid Arthritis; Splenectomy; Swelling; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17836926	EXPEDITED (15-DAY)		OT	CA-ROCHE-2607346		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Arthropathy; Asthma; Back Pain; Condition Aggravated; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Inflammation; Injection Site Inflammation; Injection Site Pruritus; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Off Label Use; Pain; Pneumonia; Pruritus; Pulmonary Fibrosis; Rheumatoid Arthritis; Septic Shock; Synovitis; Treatment Failure; Urinary Tract Infection; Urosepsis	Rituximab			S	Intravenous drip			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17837002	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202004004856			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vision Blurred	Hydroxychloroquine			S		Unk		Concordia
	Xeljanz			S	Oral	5 Mg, Bid (60/Btl)		Not Reported
	Amitriptyline			S		Unk, Dose Increased Few Months Ago		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17837076	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605992			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17837078	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605414		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Back Pain; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17837158	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605967		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Fatigue; Gait Disturbance; Inflammation; Mouth Ulceration; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis; Rotator Cuff Syndrome; Swelling; Therapeutic	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Response Decreased; Tongue Ulceration; Tooth Infection; Treatment Failure	Nystatin		S	Unknown	Not Reported
	Nystatin		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17837469	EXPEDITED (15-DAY)		OT	CA-ROCHE-2604978		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17837474	EXPEDITED (15-DAY)		DS	CA-ROCHE-2608394		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Disorder; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Rituximab			S	Intravenous drip			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17838561	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-GSH201801-000253			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral; Eye Burns; Visual Field Defect; Visual Impairment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	1 Tablet Per Day (1 Df, Every Morning), Film-Coated Tablet		Concordia
	Lanzor			C		Unk		Not Reported
	Kardegic			C		Unk		Not Reported
	Coaprovel			C		Unk		Not Reported
	Ventoline			C		Unk		Not Reported
	Rosuvastatine [Rosuvastatin]			C		Unk		Not Reported
	Hydrochlorothiazide			C		Unk		Not Reported
	Hydrochlorothiazide			C				Not Reported
	Irbesartan			C		Unk		Not Reported
	Bisoprolol			C		Unk		Not Reported
	Seretide			C		Unk		Not Reported
	Salbutamol			C		Unk		Not Reported
	Lansoprazole			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17838967	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-GSH201806-001903			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Fluid Retention; Hepatic Enzyme Increased; Herpes Zoster; Purulence; Spondylitis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qod		Concordia
	Prednisolone			S	Oral	60 Mg, Qd		Not Reported
	Prednisolone			S	Oral	45 Mg, Qd		Not Reported

Prednisolone	S	Oral	60 Mg, Qd	Not Reported
Prednisolone	S	Oral	45 Mg, Qd	Not Reported
Prednisolone	S	Oral	40 Mg, Qd	Not Reported
Prednisolone	S	Oral	35 Mg, Qd	Not Reported
Prednisolone	S	Oral	30 Mg, Qd	Not Reported
Prednisolone	S	Oral	25 Mg, Qd	Not Reported
Prednisolone	S	Oral	20 Mg, Qd	Not Reported
Prednisolone	S	Oral	17.5 Mg, Qd	Not Reported
Prednisolone	S	Oral	15 Mg, Qd	Not Reported
Prednisolone	S	Oral	12.5 Mg, Qd	Not Reported
Prednisolone	S	Oral	10 Mg, Qd	Not Reported
Prednisolone	S	Oral	9 Mg, Qd	Not Reported
Prednisolone	S	Oral	8 Mg, Qd	Not Reported
Prednisolone	S	Oral	7 Mg, Qd	Not Reported
Prednisolone	S	Oral	6 Mg, Qd	Not Reported
Prednisolone	S	Oral	5 Mg, Qd	Not Reported
Prednisolone	S	Oral	4 Mg, Qd	Not Reported
Prednisolone	S	Oral	3 Mg, Qd	Not Reported
Rituximab	S	Intravenous drip	700 Mg, Qd	Not Reported
Rituximab	S	Intravenous drip	700 Mg, Qd	Not Reported
Rituximab	S	Intravenous drip	700 Mg, Qd	Not Reported
Rituximab	S	Intravenous drip	700 Mg, Qd	Not Reported
Danazol	S	Oral	200 Mg, Qd	Not Reported
Danazol	S	Oral	300 Mg, Qd	Not Reported
Danazol	S	Oral	400 Mg, Qd	Not Reported
Danazol	S	Oral	300 Mg, Qd	Not Reported
Danazol	S	Oral	200 Mg, Qd	Not Reported
Danazol	S	Oral	100 Mg, Qd	Not Reported
Glycyron (Dl-Methionine;Glycine;Glycyrrhizic	S	Oral	9 Dosage Form, Qd	Not Reported

Acid, Ammonium Salt)				
Samtirel	C	Unk		Not Reported
Samtirel	C			Not Reported
Slow K	C	Unk		Not Reported
Slow K	C			Not Reported
Nifedipine	C	Unk		Not Reported
Halizon	C	Unk		Not Reported
Furosemide	C	Unk		Not Reported
Magmitt	C	Unk		Not Reported
Magmitt	C			Not Reported
Januvia	C	Unk		Not Reported
Januvia	C			Not Reported
Adona [Carbazochrome Sodium Sulfonate]	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17838999	EXPEDITED (15-DAY)		HO	ES-ROCHE-2608114		63 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Azitromicina			S	Oral			Not Reported
	Dolquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839102	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605181			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Gastrointestinal Toxicity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Failure	Methotrexate	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Lipitor [Atorvastatin Calcium]	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839109	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605281		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Off Label Use; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839141	EXPEDITED (15-DAY)		OT	CA-ROCHE-2035026		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Ineffective; Drug Intolerance; Feeding Disorder; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rheumatoid	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Arthritis; Stomatitis; Weight Decreased	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Varenicline Tartrate	S	Oral	Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C		Not Reported
	Esomeprazole Magnesium;Naproxen	C		Not Reported
	Prednisone	C		Not Reported
	Rosuvastatin Calcium	C		Not Reported
	Tofacitinib Citrate	C		Not Reported
	Valtrex	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839180	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605265		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Potassium Chloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839241	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2605496			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Joint Swelling; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Neutropenia; Off Label Use; Spinal Stenosis; Therapeutic Product Effect Decreased; Treatment Failure; Urinary Tract Infection; Wheelchair User	Actemra	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral	20.0 Years	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported
	Celebrex	C	Unknown		Not Reported
	Dilaudid	C	Unknown		Not Reported
	Gold	C	Unknown		Not Reported
	Morphine	C	Unknown		Not Reported
	Penicillamine	C	Unknown		Not Reported
	Tofacitinib	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839334	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605480		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Infection; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Off Label Use; Pain; Synovitis	Actemra	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839405	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3422032-00		62 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Off Label Use; Pruritus; Rash	Kaletra			S	Oral			Not Reported
	Roactemra			S	Unknown	20 Mg/Ml Concentrate		Not Reported
	Clexane			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Azithromycin			S	Oral			Not Reported
	Fidato			S	Intravenous (not otherwise specified)	2g		Not Reported
	Urbason			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839441	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608713		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Viral Upper Respiratory Tract Infection	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839657	EXPEDITED (15-DAY)		DS	CA-ROCHE-2606057		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Subcutaneous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Salazopyrin	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Not Reported
Bifidobacterium Bifidum	C		Not Reported
Celebrex	C		Not Reported
Loperamide	C		Not Reported
Pantoprazole	C		Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Simponi	C	Unknown	Not Reported
Sulfasalazine	C		Not Reported
Wellbutrin	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839754	EXPEDITED (15-DAY)		HO	CA-ROCHE-2605556			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Benzalkonium Chloride	S	Unknown	Not Reported
	Boric Acid	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Disodium Edetate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phenylephrine Hydrochloride	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Sodium Borate	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Subcutaneous	Not Reported
	Celebrex	C		Not Reported
	Ibuprofen	C		Not Reported
	Lipitor [Atorvastatin Calcium]	C		Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839787	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-02477			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Premature Delivery	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Tacrolimus			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839858	EXPEDITED (15-DAY)		DS	CA-ROCHE-2605576		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Aleve			C				Not Reported
	Arava			C				Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840168	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605008		30 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840184	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605215		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Actemra			S	Subcutaneous			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840270	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605515		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Asthenia; Condition Aggravated; Drug Ineffective; Frustration Tolerance Decreased; Impaired Work Ability; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Swelling; Musculoskeletal Stiffness; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis; Suicidal Ideation; Swelling	Actemra	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported
	Fosamax	C	Unknown	Not Reported
	Ibuprofen	C	Unknown	Not Reported
	Lisinopril	C	Unknown	Not Reported
	Vitamin D3	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840309	EXPEDITED (15-DAY)		OT	PT-TEVA-2020-PT-1241349		84 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatic Function Abnormal	Hydroxychloroquine			S	Oral	200mg Bid, 400 Mg		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840349	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606318		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Arthropathy; Blood Glucose Increased; Blood Pressure Diastolic Abnormal; Blood Pressure Diastolic Decreased; Blood Pressure Diastolic Increased; Blood Pressure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Increased; Bronchitis; Cardiac Disorder; Contusion; Croup Infectious; Drug Ineffective; Fatigue; Fibromyalgia; Foot Deformity; Gastroenteritis Viral; Headache; Heart Rate Increased; Hypersensitivity; Hypertension; Hypotension; Immunosuppression; Influenza; Infusion Related Reaction; Insomnia; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Oropharyngeal Pain; Pain; Pain In Extremity; Pertussis; Productive Cough; Rash; Stress; Therapeutic Response Decreased; Treatment Failure; Weight Decreased; Weight Increased	Methotrexate	S	Unknown	Not Reported
	Rosuvastatin Calcium	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Folic Acid	C		Not Reported
	Humalog	C	Unknown	Not Reported
	Sertraline Hydrochloride	C		Not Reported
	Synthroid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840377	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2020M1051907		11 YR	Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Infection; Off Label Use; Shock	Lopinavir/Ritonavir			S	Oral	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Methylprednisolone			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840422	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608715		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Gamma-Glutamyltransferase Increased; Hepatic Steatosis; Upper Respiratory Tract Infection	Rituximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840536	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605589		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Back Pain; Drug Ineffective; Infection; Influenza; Pneumonia; Tooth Fracture; Vaccination Site Cellulitis; Vaccination Site Induration	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Cortisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Pneumococcal Vaccine			S	Unknown	For 1 Month		Not Reported
	Andriol			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Eprosartan Mesilate;Hydrochlorothiazide			C				Not Reported
	Estrogel			C	Unknown			Not Reported
	Nifedipine			C				Not Reported
	Prometrium [Progesterone]			C				Not Reported
	Rosuvastatin Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840626	EXPEDITED (15-DAY)		CA, OT	FR-PFIZER INC-2020208534			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Achromotrichia Congenital; Maternal Exposure During Pregnancy	Zithromax			S	Transplacental	250 Mg, 1x/Day		Pfizer
	Hydrocortisone Roussel [Hydrocortisone Acetate]			S	Transplacental	100 Mg, 1x/Day		Not Reported
	Parlodel			S	Transplacental	20 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Transplacental	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840766	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1051938		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Intentional Product Misuse; Off Label Use	Azithromycin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840956	EXPEDITED (15-DAY)		DE, OT	BE-ADVANZ PHARMA-202005005958			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840986	EXPEDITED (15-DAY)		HO	CA-ROCHE-2605191		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cardiovascular Disorder; Condition Aggravated; Cystitis; Deformity; Depressed Mood; Dermatitis; Drug	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported

Ineffective; Encephalitis; Encephalitis Brain Stem; Fall; Fibromyalgia; Immobile; Immune System Disorder; Immunodeficiency; Joint Destruction; Loss Of Personal Independence In Daily Activities; Memory Impairment; Pain; Peripheral Swelling; Psychiatric Symptom; Rheumatoid Arthritis; Rib Fracture; Scar; Seizure; Sepsis; Spinal Deformity; Vomiting	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Furosemide	C	Unknown	Not Reported
	Hydromorph Contin	C	Unknown	Not Reported
	Lyrica	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17841249	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605225		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Androgenetic Alopecia; Aphthous Ulcer; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Increased; Diffuse Alopecia; Drug Ineffective; Heart Rate Decreased; Infection; Infusion Related Reaction; Nasopharyngitis; Rash; Stomatitis; White Blood Cell Count Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Asa			C	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Candesartan			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17841275	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2020-ES-1240532		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Thrombocytopenia	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Enoxaparina (2482a)			S	Subcutaneous	160 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17841284	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1240452		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Gastrointestinal Pain	Hidroxicloroquina (2143a)			S	Oral	200 Mg		Teva
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	1 Dosage Form		Not Reported
	Omeprazol (2141a)			C	Oral	20 Mg		Not Reported
	Paracetamol 1.000 Mg 40 Comprimidos			C	Oral	1 Gm		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17841446	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605474		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Joint Swelling; Off Label Use; Pneumonia; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Infliximab	S	Unknown	Not Reported
Lidocaine Hydrochloride	S	Subcutaneous	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Cefalexin	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Enbrel	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17841450	EXPEDITED (15-DAY)		OT	PT-TEVA-2020-PT-1241324		59 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatic Function Abnormal	Hydroxychloroquine			S	Oral	200 Mg Bid. Unit Dose: 400 Mg		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17841644	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2020205717		69 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bilirubin Increased; Coronavirus Infection; Drug Ineffective; Hepatic Function Abnormal; Hypoxia; Inflammation; Localised Oedema; Pneumonia;	Lederfoline			S		Unk		Pfizer
	Tazocilline			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Lovenox [Enoxaparin Sodium]			S	Subcutaneous	2 Df, 1x/Day (2x/Day (8000 Ui)		Not Reported
	Perfalgan			S		1 G, 4x/Day		Not Reported
	Bactrim			S		Unk		Not Reported
	Inexium [Esomeprazole Magnesium]			S	Intravenous (not	40 Mg, 1x/Day		Not Reported

Pseudomonas Infection; Severe Acute Respiratory Syndrome; Spinal Disorder; Stenotrophomonas Infection	Rocephine	S	otherwise specified)	Unk	Not Reported
	Mucomyst [Acetylcysteine]	S		4 Df, 1x/Day, (1 Df 4x/Day (Sachet Sng))	Not Reported
	Dextromethorphan Hydrobromide	S		Unk	Not Reported
	Catapressan [Clonidine Hydrochloride]	S		Unk	Not Reported
	Claventin [Clavulanate Potassium;Ticarcillin Disodium]	S		Unk	Not Reported
	Tavanic	S		500 Mg, 2x/Day	Not Reported
	Eupressyl [Urapidil]	S		Unk	Not Reported
	Fortum [Ceftazidime]	S		2 G, 3x/Day	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Unk	Not Reported
	Tranxene	S		2.5 Mg, Per Hour	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17841669	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1051990		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Off Label Use	Enoxaparin			S	Subcutaneous	60 Milligram, Qd, 60 Mg		Not Reported
	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Hidroxicloroquina /00072601/			S	Oral	400 Mg Dia		Mylan
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17841688	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608333			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; C-Reactive Protein Increased;	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not	Therapy Duration: 397		Not Reported

Cataract; Drug Ineffective; Laboratory Test Abnormal; Off Label Use; Red Blood Cell Sedimentation Rate Abnormal			otherwise specified)	Days		
	Arava	S	Unknown			Not Reported
	Arava	S	Oral			Not Reported
	Celebrex	S	Oral			Not Reported
	Enbrel	S	Unknown	Therapy Duration: 6 Years		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S	Unknown	Therapy Duration: 560		Not Reported
	Orencia	S	Unknown	Therapy Duration: 471 Days		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Therapy Duration: 10 Years		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 471 Days		Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Xeljanz	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17841767	EXPEDITED (15-DAY)		HO	NVSC2020US147932		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Intentional Overdose; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	10-11 G		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17841807	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605509		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Blood Creatinine Increased;	Actemra			S	Unknown			Not Reported

Diarrhoea; Drug Ineffective; Limb Discomfort; Musculoskeletal Discomfort; Off Label Use; Pain; Pharyngeal Oedema; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Penicillin G [Benzylpenicillin]	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Arava	C		Not Reported
	Hydroxychloroquine	C		Not Reported
	Methotrexate	C		Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17842163	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042185			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17842419	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605453		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Neutropenia; Off Label Use; Red Blood Cell Sedimentation Rate Increased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Urinary Tract Infection	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17842449	EXPEDITED (15-DAY)		DE, HO	SK-ROCHE-2388944		57 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cerebral Infarction; Dizziness; Hypotension; Intentional Product Use Issue; Mental Impairment; Off Label Use; Pneumonia; Progressive Multifocal Leukoencephalopathy; Respiratory Failure; Speech Disorder; Tremor	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cyclosporine			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported

	Prednisone		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17842621	EXPEDITED (15-DAY)		LT	CA-ROCHE-2608325		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disease Progression; Dysphonia; Dyspnoea; Odynophagia; Product Use In Unapproved Indication; Rheumatoid Arthritis; Stridor	Rituximab			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17842629	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609222			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17842639	EXPEDITED (15-DAY)		OT	CA-ROCHE-2604987			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Hand Deformity; Joint Stiffness; Nausea; Pain; Therapeutic Product Effect Decreased; Thyroid Disorder	Actemra	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17842640	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605519		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Synovitis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17842706	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605538		22 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra		S	Subcutaneous		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Enbrel		S	Unknown	5.0 Months	Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Methotrexate		S	Oral		Not Reported
	Orencia		S	Subcutaneous	8.0 Months	Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Xeljanz		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17845062	DIRECT	Y	DE			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Hydroxychloroquine			S	Oral			Actavis
	Actemra			S	Intravenous (not otherwise specified)	Other Frequency:X1;		Genentech

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	15317460	EXPEDITED (15-DAY)		OT	CA-ROCHE-2172797		16 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Crohn'S Disease; Drug Hypersensitivity; Drug	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported

Intolerance; Gait Disturbance; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Oral	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Folic Acid	C	Oral	Not Reported
	Leflunomide	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Tofacitinib Citrate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17023732	EXPEDITED (15-DAY)		OT	CA-ROCHE-2459446		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Swelling; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis; Suicidal Ideation	Actemra	S	Unknown	Dosage Form : Not Specified	Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Dosage Form : Not Specified	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Unknown	Dosage Form : Not Specified	Not Reported
	Alendronate Sodium	C	Unknown		Not Reported
	Fosamax	C	Unknown		Not Reported
	Ibuprofen	C	Unknown	Dosage Form : Not Specified	Not Reported
	Lisinopril	C	Unknown		Not Reported
	Vitamin D3	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17260308	EXPEDITED (15-DAY)		OT	CA-ROCHE-2517545		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Off Label Use; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

Apo-Leflunomide	S	Oral		Not Reported
Asa	C	Unknown		Not Reported
Ergocalciferol	C	Unknown		Not Reported
Lantus	C	Subcutaneous		Not Reported
Lozide [Indapamide]	C	Unknown		Not Reported
Metformin	C	Unknown		Not Reported
Naprosyn [Naproxen]	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Ramipril	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17295895	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524847		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Limb Operation; Pain; Peripheral Swelling; Rash; Swelling; Tendon Operation; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution For Infusion		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Benzylpenicillin			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Plaquenil [Hydroxychloroquine Sulfate]	S	Oral			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution For Infusion		Not Reported
Rocuronium Bromide	S	Unknown			Not Reported
Sodium Aurothiomalate	S	Parenteral			Not Reported
Sulfamethoxazole/Trimethoprim	S	Unknown			Not Reported
Methotrexate	S	Unknown	Solution		Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17351049	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531131		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Lyrica	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17406344	EXPEDITED (15-DAY)		OT	CA-ROCHE-2541854			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17454837	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552651		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction;	Rituximab			S	Intravenous (not			Not Reported

Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Red Blood Cell Sedimentation Rate Increased; Urticaria			otherwise specified)		
	Adalimumab	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Infliximab	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Parenteral		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Simponi	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Subcutaneous		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Azathioprine	C			Not Reported

Ciclosporin	C	Unknown		Not Reported
Minocycline	C			Not Reported
Penicillamine	C			Not Reported
Prednisone	C			Not Reported
Actemra	C	Unknown		Not Reported
Cyclosporine	C			Not Reported
D-Penicillamine	C			Not Reported
Phenylbutazone	C			Not Reported
Prednisolone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17559399	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2018-03346		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Oral	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Oral	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution		Not Reported
	Remicade			S	Intravenous (not			Not Reported

		otherwise specified)		
Rituxan	S	Intravenous (not otherwise specified)	Unknown, Solution	Not Reported
Gold	S	Intramuscular	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Unknown	Not Reported
Imuran	S	Unknown	Unknown	Not Reported
Leflunomide	S	Unknown	Unknown	Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Oral	Unknown	Not Reported
Plaquenil	S	Unknown	Unknown	Not Reported
Methotrexate Sodium	S	Unknown	Unknown	Not Reported
Actemra	S	Unknown	Unknown	Not Reported
Humira	S	Subcutaneous		Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituximab	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
Sulfasalazine	C	Unknown	Unknown	Not Reported
Wellbutrin	C	Unknown	Unknown	Not Reported
Xeljanz	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17675643	EXPEDITED (15-DAY)		DE, OT	ES-HETERO-HET2020ES00415		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Levofloxacin			S	Unknown	Unk		Hetero
	Hydroxychloroquine			S	Oral	200 Mg, Qd		Not Reported

Azitromicina	S	Oral	500 Mg, Qd		Not Reported
Lopinavir/Ritonavir	S	Oral	2 Dosage Form, Bid		Not Reported
Tacrolimus	S	Oral	Unk		Not Reported
Ceftriaxone	C	Unknown	Unk		Not Reported
Enoxaparin Sodium	C	Unknown	Unk, Qd		Not Reported
Prednisona	C	Unknown	Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17710430	EXPEDITED (15-DAY)		DE	IT-TEVA-2020-IT-1226892		70 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Transaminases Increased	Azitromicina Teva 500 Mg Compresse Rivestite Con Film			S	Oral	500 Mg		Not Reported
	Plaquenil			S	Oral	400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17763532	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1231868		56 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Multiforme; Off Label Use; Oral Disorder; Rash Pruritic; Rash Pustular; Rash Vesicular; Stevens-Johnson Syndrome	Hydroxychloroquine			S	Oral	400 Mg		Teva
	Symtuza			S	Oral	1 Dosage Forms		Not Reported
	Triumeq			S	Oral	1 Dosage Forms		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17777966	EXPEDITED (15-DAY)		HO, OT	LV-ROCHE-2599087		12 YR	Female	LVA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Pneumonitis; Systemic Lupus Erythematosus; Weight	Roactemra			S	Intravenous (not otherwise specified)			Not Reported
	Roactemra			S				Not Reported

Decreased	Methylprednisolone	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Azithromycin	S	Unknown		Not Reported
	Mycophenolate Mofetil	C	Unknown	For Short Time Period (1-2 Weeks). Stopped Due To Skin Eruptions	Not Reported
	Rituximab	C	Unknown		Not Reported
	Cyclophosphamide	C	Unknown	For Short Time Period (1-2 Weeks)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17795926	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235484		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Reactine [Cetirizine]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17842784	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609160			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Drug Ineffective; Joint Swelling	Rituximab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown	Not Specified		Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Amitriptyline			C				Not Reported
	Cefazolin			C				Not Reported
	Clindamycin			C				Not Reported
	Prednisone			C	Unknown			Not Reported
	Tylenol W/Codeine No. 3			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17842787	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609352		71 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Dizziness; Nausea; Vomiting	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Rituximab	S	Intravenous drip	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17842862	EXPEDITED (15-DAY)		OT	NVSC2020IT148686		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Off Label Use	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Novartis
	Mycophenolate Mofetil			S	Unknown	1 Df, Qd (Unk Unk, Qd)		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd		Not Reported
	Prednisone			S	Unknown	50 Mg, Qd, Tapering Dose		Not Reported
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisone			S	Unknown	25 Mg Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	12.5 Mg, Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	12.5 Mg, Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	10 Mg, Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	7.5 Mg, Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	10 Mg, Qd, Dose Tapering		Not Reported
	Envarsus			S	Unknown	1 Df, Qd (Unk, Qd)		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Immunoglobulin I.V			C	Unknown	Unk		Not Reported

	Rituximab		C	Unknown	Unk	Not Reported
	Methylprednisolone		C	Unknown	Unk (Pulses)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17842917	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606101			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Chest Pain; Eye Ulcer; Foot Deformity; Hand Deformity; Headache; Injection Site Reaction	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17842947	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606357			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Off Label Use; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Tylenol	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17842985	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606840			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843009	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606641			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

Orencia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Subcutaneous	Not Reported
Sulfasalazine	S	Subcutaneous	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Certolizumab Pegol	S	Subcutaneous	Not Reported
Fosamax	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843012	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606173		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Intestinal Perforation	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843015	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-026288		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843201	EXPEDITED (15-DAY)		HO	CA-ROCHE-2606270		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation; Choking; Condition Aggravated; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Ear Pain; Facial Pain; Facial Paralysis; Fatigue; Fibromyalgia; Foot Deformity; Gait Disturbance; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Influenza Like Illness; Insomnia; Joint Range Of Motion Decreased; Lipoma; Melanocytic Naevus; Musculoskeletal Stiffness; Nasal Discomfort; Nasopharyngitis; Nausea; Night Sweats; Oropharyngeal	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Calcium Folinate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Acetaminophen;Oxycodone Hydrochloride			C	Oral			Not Reported

Discomfort; Osteoporosis; Pain; Pain In Extremity; Pain In Jaw; Pelvic Prolapse; Peripheral Coldness; Platelet Count Decreased; Post Procedural Infection; Rheumatoid Arthritis; Rhinorrhoea; Skin Mass; Therapeutic Product Effect Decreased; Throat Irritation	Celebrex	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Fentanyl	C	Unknown	Not Reported
	Gabapentin	C	Oral	Not Reported
	Metformin Hydrochloride;Sitagliptin	C	Oral	Not Reported
	Oxycodone Hydrochloride	C	Unknown	Not Reported
	Perindopril Erbumine	C	Oral	Not Reported
	Rabeprazole	C	Oral	Not Reported
	Ranitidine	C	Oral	Not Reported
	Rosuvastatin Calcium	C	Oral	Not Reported
	Sitagliptin	C	Oral	Not Reported
	Synthroid	C	Oral	Not Reported
	Tylenol	C	Unknown	Not Reported
	Zopiclone	C	Oral	Not Reported
	Zostavax	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843211	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606334			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843212	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606521		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843214	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606426			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nausea; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting; White Blood Cell Count Decreased	Actemra			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843218	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606612		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis;	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843226	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606514		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Actemra			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843228	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606627			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use; Prescribed Underdose; Product Use Issue	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843240	EXPEDITED (15-DAY)		HO	CA-ROCHE-2609163			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gamastan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843247	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606810		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Fibromyalgia; Lymphoedema; Obesity; Pneumocystis Jirovecii Pneumonia; Pulmonary Embolism	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Calcium/Vitamin D3			C				Not Reported
	Hydrocortisone			C	Unknown			Not Reported
	Pantoloc [Pantoprazole]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tylenol 8 Hr Arthritis Pain			C	Unknown			Not Reported
	Xarelto			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843266	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605626		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Swelling; Candida Infection; Condition Aggravated;	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Drug Ineffective; Drug Interaction; Headache; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nausea; Neoplasm Malignant; Off Label Use; Oral Candidiasis; Pain; Peripheral Swelling; Prescribed Overdose; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Thyroid Neoplasm; Toxicity To Various Agents; Treatment Failure	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Celebrex	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Duration :7 Years	Not Reported
	Humira	S	Unknown	Duration :7 Years	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous	Duration: 13.0 Years	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tofacitinib	S	Unknown		Not Reported
	Tofacitinib Citrate	S	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843333	EXPEDITED (15-DAY)		OT	CA-ROCHE-2604955			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Neutropenia; Off Label Use; Osteoarthritis; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Therapy Partial Responder; Urinary Tract Infection	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	Frequency: Cyclical		Not Reported
	Enbrel			C	Subcutaneous			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843367	EXPEDITED (15-DAY)		HO	CA-ROCHE-2605541		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anti-Neutrophil Cytoplasmic Antibody Positive Vasculitis; Arthralgia; Chest Pain; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Hypersensitivity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Proteinuria; Rheumatoid Arthritis; Treatment Failure; Vasculitis	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Oral			Not Reported
	Azathioprine Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Gold			S	Intramuscular			Not Reported

	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Infliximab	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Penicillamine	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Cyclophosphamide	C	Intravenous (not otherwise specified)		Not Reported
	Docusate Sodium	C	Oral		Not Reported
	Doxycycline	C	Oral		Not Reported
	Elavil [Amitriptyline Hydrochloride]	C			Not Reported
	Prednisone	C	Oral		Not Reported
	Sulfasalazine	C	Oral		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Tobramycin	C	Unknown	0.3 Percent	Not Reported
	Wellbutrin	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843368	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605484		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; Arthropathy;	Actemra			S	Intravenous (not			Not Reported

Asthma; Drug Ineffective; Drug Intolerance; Fatigue; Fine Motor Skill Dysfunction; Gastric Disorder; Gastrointestinal Disorder; Hip Arthroplasty; Hypertension; Inflammation; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Motor Dysfunction; Musculoskeletal Pain; Musculoskeletal Stiffness; Off Label Use; Pain; Pruritus; Rheumatoid Factor Positive; Seronegative Arthritis; Swelling; Synovitis; Therapeutic Product Effect Decreased; Urticaria			otherwise specified)	
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843404	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606876			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Glossodynia; Maternal Exposure During Pregnancy; Pain;	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cortisone Acetate	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843411	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606364			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Arava	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Simponi	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843412	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608827			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843413	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609657		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Rash; Treatment Failure; Urticaria	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843454	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606986			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

Fosamax	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Topicort [Desoximetasone]	S	Topical	Not Reported
Cimzia	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843455	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606569			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

Failure; Wound	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Phosphate	S	Unknown	Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843464	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606667		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Pain; Pain In Extremity; Peripheral Swelling; Red	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Codeine	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843468	EXPEDITED (15-DAY)		CA	CA-ROCHE-2608792			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Drug Ineffective; Drug Intolerance; Insomnia; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Naprosyn [Naproxen]			S	Oral			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported
	Orencia			S	Endocervical			Not Reported
	Rituximab			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported

	Xeljanz	C		Not Reported
	Leflunomide	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17843469	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608976		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2020	17064085	EXPEDITED (15-DAY)		OT	CA-ROCHE-2469680		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported

Label Use; Prescribed Underdose	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2020	17552505	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021419			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	162 Milligram		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Azathioprine			C	Unknown	162 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2020	17843599	EXPEDITED (15-DAY)		OT	CA-ROCHE-2586473		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Renal Failure; Treatment Failure	Mycophenolate Mofetil		S	Unknown	Not Reported
	Azathioprine		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2020	17843654	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042221			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2020	17843673	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609647			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Frequency: Every 1 Days		Not Reported

	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2020	17843674	EXPEDITED (15-DAY)		HO	CA-ROCHE-2608807		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthropathy; Breast Cancer Stage Iii; Condition Aggravated; Depression; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gait Disturbance; Gait Inability; Hand Deformity; Infection; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Nausea; Off Label Use; Ovarian Cancer; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Sleep Disorder; Therapeutic Product Effect Incomplete; Unevaluable Event; Urticaria	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2020	17843675	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609334		71 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Dizziness; Nausea; Vomiting	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Atorvastatin Calcium			C	Unknown			Not Reported
	Irbesartan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2020	17843730	EXPEDITED (15-DAY)		HO	CA-ABBVIE-20K-028-3424015-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Burns First Degree	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2020	17843746	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042236			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	11883803	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1687418		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Naproxen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Every 2 Days		Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 731.0 Nos		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C				Not Reported

Folic Acid	C			Not Reported
Celebrex	C	Unknown		Not Reported
Metformin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	12222790	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-020922		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hepatic Enzyme Increased; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Off Label Use; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Q4wk		Bristol Myers Squibb
	Humira			S	Subcutaneous	Unk		Not Reported
	Gabapentin			S	Oral	100 Milligram, Bid		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Celebrex			S	Unknown			Not Reported
	Apo Celecoxib			S	Oral	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, Qmo		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Oxycontin			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Subcutaneous	1 Dosage Form, Qwk		Not Reported
	Sulfasalazine			S	Oral	2.5 Gram, Qd		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Qd		Not Reported
	Sulfasalazine			S	Oral	2.5 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	400 Milligram, Qd		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, Q3wk		Not Reported
	Apo Gabapentin			S	Oral	100 Milligram, Bid		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported

Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Nortriptyline Hydrochloride;Perphenazine	S	Oral	10 Milligram, Qd	Not Reported
	Fentanyl Citrate	S	Epidural		Not Reported
	Fentanyl Matrix	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	400 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	1 Dosage Form, Qwk	Not Reported
	Omega 3 [Fish Oil;Tocopherol]	C	Unknown	1200 Milligram, Bid	Not Reported
	Multivitamin [Ascorbic Acid;Calcium Pantothenate;Ergocalciferol;Nicoti	C	Unknown	Unk	Not Reported
	Tecta	C	Unknown	40 Mg, Qd	Not Reported
	Diphenoxylate	C	Unknown	2.5 Milligram, Qd	Not Reported
	Diphenoxylate	C	Unknown	1 Dosage Form, Qd	Not Reported
	Vitamin D [Ergocalciferol]	C	Unknown	400 Unit, Qd	Not Reported
	Actonel	C	Unknown	36 Milligram, Qwk	Not Reported
	Prednisone	C	Unknown	5 Milligram, Qd	Not Reported
	Prednisone	C	Unknown	5 Milligram 1 Every 2 Hour	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Q4wk	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Q2wk	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Qmo	Not Reported
	Calcium	C	Unknown	Unk	Not Reported
	Acetaminophen W/Oxycodone	C	Unknown	1 Dosage Form Prn	Not Reported
	Biotin;Calcium Carbonate;Colecalciferol;Folic Acid	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown	400 International Unit, Qd	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	40 Milligram, Bid	Not Reported
	Esomeprazole	C	Unknown	400 Milligram, Bid	Not Reported

Ferrous Gluconate	C	Unknown	300 Milligram, Qd	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Milligram	Not Reported
Pyridoxine	C	Unknown	Unk	Not Reported
Nasonex	C	Nasal	2 Dosage Form, Bid	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Milligram, Qd	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Qd	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram 1 Every 1 Hour	Not Reported
Tylenol	C	Oral	1000 Milligram, Qd	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	1 Dosage Form, Qd	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Milligram, Bid	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 International Unit, Qd	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Docosahexaenoic Acid	C	Unknown	Unk Unk, Qd	Not Reported
Xeljanz	C	Unknown	5 Milligram, Bid	Not Reported
Xeljanz	C	Unknown	5 Milligram, Qd	Not Reported
Xeljanz	C	Unknown	5 Milligram	Not Reported
Vitamin B12 Aaa	C	Unknown		Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown	1200 Milligram, Bid	Not Reported
Ferrous Fumarate	C	Unknown	Unk	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk Unk, Qd	Not Reported

Thiamine Mononitrate	C	Unknown	Unk	Not Reported
Trazodone	C	Unknown	Unk	Not Reported
Vitamin A Nos	C	Unknown	Unk	Not Reported
Vitamin B 12 [Cyanocobalamin]	C	Unknown	Unk	Not Reported
Vitamin C Acid	C	Unknown	Unk	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Milligram 1 Every One Hour	Not Reported
Nexium [Esomeprazole Sodium]	C	Unknown	40 Milligram, Bid	Not Reported
Genteal [Hypromellose]	C	Unknown		Not Reported
Oxycodone Hydrochloride;Oxycodone Terephthalate;Paracetamol	C	Unknown	1 Dosage Form, As Required	Not Reported
Perphenazine	C	Unknown	40 Milligram, Qd	Not Reported
Perphenazine	C	Oral	10 Milligram	Not Reported
Percocet [Oxycodone Hydrochloride;Paracetamol]	C	Unknown	1 Dosage Form, Prn	Not Reported
Vitamin E [Tocopherol]	C	Unknown	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	C	Unknown	Unk	Not Reported
Celecoxib	S	Oral	Unk	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Milligram, Bid	Not Reported
Epa Dha 720	C	Unknown	Unk	Not Reported
Fergon	C	Unknown	300 Milligram, Qd	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Lomotil [Loperamide Hydrochloride]	C	Unknown	Unk	Not Reported
Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown		Not Reported
Omega-3 [Salmo Salar Oil]	C	Unknown	Unk	Not Reported
Omega-3 Fatty Acids	C	Unknown	1200 Milligram, Bid	Not Reported
Pantoprazole	C	Unknown	40 Milligram, Qd	Not Reported

	Pantoprazole	C	Unknown	400 Milligram	Not Reported
	Sodium Ascorbate	C	Unknown	Unk	Not Reported
	Sodium	C	Unknown	Unk	Not Reported
	Cholecalciferol	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	1000 Milligram, Qd	Not Reported
	Risedronate Sodium	C	Unknown	36 Milligram, Qwk	Not Reported
	D-Alpha Tocopheryl Acetate	C	Unknown	1200 Milligram	Not Reported
	Apo-Gabapentin	C	Oral	100 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	12330313	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1750335		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg X 2, Therapy Duration: 2 Years Therapy Duration: 12 Months		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg X 2		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg X 2		Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown	Therapy Duration: 10 Months		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Therapy Duration: 20		Not Reported

Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer				Years	
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Codeine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 365	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Methotrexate Sodium	S	Oral	Therapy Duration: 20 Years	Not Reported
	Methotrexate Sodium	S	Oral	Therapy Duration: 20 Years	Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Alendronic Acid	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Celebrex	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Etanercept	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported

	Naproxen	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Prednisolone	C	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	12370677	EXPEDITED (15-DAY)		DS, HO, OT	CA-ROCHE-1756598		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Arthropathy; Breath Sounds Abnormal; Condition Aggravated; Contraindicated Product Administered; Hepatic Enzyme Increased; Inflammation; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Therapy Duration: 365 Nos		Not Reported
	Methotrexate Sodium			S	Unknown	Unknown Dose And Frequency, Discontinued		Not Reported
	Enbrel			S	Subcutaneous	Unknown Dose And Frequency		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported

Remicade	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	End Date: Unknown	Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Intravenous (not otherwise specified)		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Xeljanz	C	Oral		Not Reported
Prednisone	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Acetylsalicylic Acid	C	Unknown		Not Reported
Actonel	C	Unknown		Not Reported
Alprazolam	C	Unknown		Not Reported
Amlodipine	C	Unknown		Not Reported
Arava	C	Unknown		Not Reported
Bisoprolol Fumarate	C	Unknown		Not Reported
Celebrex	C	Unknown		Not Reported
Ergocalciferol	C	Unknown		Not Reported
Esomeprazole	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Iron Sucrose	C	Unknown		Not Reported

Metformin	C	Unknown	Not Reported
Morphine Sulfate	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Paroxetine	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Intracardiac	Not Reported
Risedronate	C	Unknown	Not Reported
Simponi	C	Subcutaneous	Not Reported
Simvastatin	C	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Telmisartan	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	12769617	EXPEDITED (15-DAY)		OT	CA-ROCHE-1832761			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Off Label Use; Treatment Failure; Vomiting	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	12838058	EXPEDITED (15-DAY)		OT	CA-ROCHE-1840826		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Joint Swelling; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Synovitis; Vomiting	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown	Solution For Injection In Pre-Filled Syringe		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Synthroid			C				Not Reported
	Remicade			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	12859898	EXPEDITED (15-DAY)		OT	CA-ROCHE-1695809		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Joint Swelling; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration 4 Months		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 7.0 Month(S)		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown	Therapy Duration: 10.0 Month(S)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	12930360	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092641		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Apo-Leflunomide	S	Unknown	Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Cimzia	S	Subcutaneous	Unk		Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Remicade	S	Unknown			Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported
	Desoximetasone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	12985318	EXPEDITED (15-DAY)		OT	CA-ROCHE-1859492		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Off Label Use; Synovitis; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)	
	Hydroxychloroquine Sulphate	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Amitriptyline Hydrochloride	S	Unknown	Not Reported
	Amitriptyline Hydrochloride	S	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Calcium Carbonate	C	Unknown	Not Reported
	Cymbalta	C		Not Reported
	Elavil [Amitriptyline Hydrochloride]	C	Unknown	Not Reported
	Hydrochlorothiazide	C		Not Reported
	Imitrex [Sumatriptan]	C		Not Reported
	Lyrica	C	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported
	Premarin	C		Not Reported
	Tenormin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Amitriptyline	C		Not Reported
	Sumatriptan	C		Not Reported
	Sumatriptan Succinate	C		Not Reported
	Tofacitinib	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	13114444	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20170105843		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Adverse Event; Alanine Aminotransferase Increased; Ankylosing Spondylitis; Arthralgia; Aspartate Aminotransferase Increased; Asthenia;	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Asthma; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Blood Test Abnormal; Body Temperature Decreased; Bone Lesion; C-Reactive Protein Increased; Cataract; Chest Pain; Chills; Contraindicated Product Administered; Contusion; Deep Vein Thrombosis; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Dysphonia; Dyspnoea; Erythema; Fall; Fatigue; Feeling Abnormal; Gastrointestinal Disorder; Gastrointestinal Pain; Granuloma Skin; Heart Rate Increased; Hepatic Enzyme Abnormal; Hypercalcaemia; Hypersensitivity; Infection; Inflammation; Influenza; Infusion Related Reaction; Lethargy; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Lower Respiratory Tract Infection; Morton'S Neuralgia; Muscular Weakness; Musculoskeletal Disorder; Musculoskeletal Stiffness; Mycotic Allergy; Nausea; Neuropathy Peripheral;	Enbrel	S	Unknown		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous	Start Date: 5th Of Unspecified Month	Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous	Start Date: 1st Of Unspecified Month	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Start Date: 8th Of Unspecified Month	Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown	Start Date: On 10th Of Unspecified Month In 2011.	Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Alendronate	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported

Oral Discomfort; Pain; Pain In Extremity; Panniculitis; Peripheral Swelling; Product Use Issue; Productive Cough; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Respiratory Tract Congestion; Rheumatoid Arthritis; Rheumatoid Nodule; Rhinorrhoea; Skin Necrosis; Skin Ulcer; Speech Disorder; Therapeutic Response Decreased; Ulcer	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Oral	4 Years	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Intravenous (not otherwise specified)		Not Reported
	Codeine	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Start Date: 1st Of Unspecified Month	Not Reported
	Methotrexate	S	Unknown	Start Date: 5th Of	Not Reported

			Unspecified Month	
Methotrexate	S	Unknown	Start Date: 5th Of Unspecified Month	Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown	Start Date: 1st Of Unspecified Month	Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Myochrysine	S	Parenteral		Not Reported
Myochrysine	S	Parenteral		Not Reported
Myochrysine	S	Parenteral		Not Reported
Myochrysine	S	Parenteral		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Orencia	S	Unknown	Start Date: 1st Of Unspecified Month	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Rituximab	S	Unknown		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Alendronic Acid	S			Not Reported
Arava	S	Unknown		Not Reported

	Humira	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Ergocalciferol	S	Unknown	Not Reported
	Pantoprazole	S	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Prednisolone	C		Not Reported
	Desoximetasone	C		Not Reported
	Naproxen	C		Not Reported
	Plaquenil /00072602/	C		Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Sulfasalazine	C		Not Reported
	Symbicort	C		Not Reported
	Tramadol Hydrochloride	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	13772085	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091773			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Drug Ineffective; Foot Deformity; Hand Deformity; Intentional Product Use Issue; Joint Swelling; Leukopenia; Loss Of Personal Independence In Daily Activities; Pain In	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Visual Impairment	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Phosphate	S	Unknown	400 Mg, Qd	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	400 Milligram, Qd	Not Reported
	Sulfasalazine	S	Oral	1 G, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram	Not Reported
	Solu-Medrol	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Paracetamol	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	13854687	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070309			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported

Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk		Not Reported
Apo-Leflunomide	S	Oral	Unk		Not Reported
Methotrexate	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Leflunomide	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	14633459	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-019566		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	15461181	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190731			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tooth Infection; Weight Decreased	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Actonel	C	Unknown	Not Reported
	Risedronate Sodium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	15622674	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557515-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Cough; Drug Ineffective; Influenza; Nasopharyngitis; Nausea; Psoriasis; Rash	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	15629653	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2557267-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Imuran			C	Unknown			Not Reported
	Azathioprine			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	15681461	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2575030-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Contraindicated Product Administered; Drug Ineffective; Drug	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Intolerance; Extremity Contracture; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Aspirin	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Not Reported
	Orencia	C		Not Reported
	Acetylsalicylic Acid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	15802644	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2616920-00		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Marijuana			S	Unknown			Not Reported

Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Photosensitivity Reaction; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Stomatitis; Urticaria	Methotrexate	S	Unknown	Not Reported
	Minocycline	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Cannabis Sativa	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lyrica	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	15803741	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2618078-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Hydroxychloroquine	S	Unknown		Not Reported
	Celebrex	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	15958056	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170820946		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Reaction; Blood Iron Abnormal; Contraindication To Vaccination; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Laryngeal Disorder; Nausea; Off Label Use; Pain; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	0.8 Ml		Not Reported
	Humira			S	Subcutaneous	0.8 Ml		Not Reported
	Humira			S	Subcutaneous	0.8 Ml		Not Reported
	Humira			S	Subcutaneous			Not Reported

Gold	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Certolizumab	S	Subcutaneous	Not Reported
Azathioprine	S	Unknown	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Certolizumab Pegol	S	Unknown	Not Reported
Lyrica	S	Oral	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Cellcept /01275102/	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Pregabaline	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Piroxicam	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	16189081	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP011205		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Amitriptyline			S	Unknown			Apotex
	Naproxen Sodium			S	Unknown	Unk		Apotex

Azathioprine	S	Unknown			Apotex
Cyclosporine	S	Unknown			Apotex
Folic Acid	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown			Apotex
Leflunomide	S	Unknown			Apotex
Oxycodone	S	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported
Medroxyprogesterone	S	Unknown	Unk		Not Reported
Depo-Provera	S	Unknown			Not Reported
Etanercept	S	Unknown	25 Mg, Q.Wk.		Not Reported
Infliximab	S	Unknown	400 Mg, Total		Not Reported
Methotrexate	S	Unknown			Not Reported
Naprosyn /00256201/	S	Unknown			Not Reported
Rituximab	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Anakinra	C	Unknown	Unk		Not Reported
Cyclosporine	C	Unknown	Unk		Not Reported
Depo-Provera	C	Unknown	Unk		Not Reported
Hydroxychloroquine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	16480475	EXPEDITED (15-DAY)		OT	US-MALLINCKRODT-T201804782			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Arthralgia; Arthritis; Back Pain; Blood Cholesterol Abnormal; Blood Sodium Increased; Blood Uric Acid Increased; Chest Pain; Depression; Dizziness; Eye	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 Ml, 1 Time Weekly Sunday		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 Ml, 1 Time Weekly Sunday		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 Ml, 1 Time Weekly (Sunday)		Mallinckrodt

Haemorrhage; Fatigue; Gait Disturbance; Headache; Heart Rate Increased; Hyperhidrosis; Hypertension; Hypoaesthesia; Immune System Disorder; Infection; Influenza; Insomnia; Malaise; Memory Impairment; Menorrhagia; Mental Fatigue; Mobility Decreased; Mood Altered; Muscle Spasms; Muscular Weakness; Musculoskeletal Pain; Nausea; Neck Pain; Nervousness; Pain; Pain In Extremity; Pallor; Papilloedema; Poisoning; Polymenorrhoea; Product Dose Omission; Proteinuria; Renal Impairment; Sciatica; Sensitivity To Weather Change; Somnolence; Stress; Systemic Lupus Erythematosus; Vision Blurred; Visual Impairment; Vomiting; Weight Decreased	Repository Corticotropin Injection	S	Subcutaneous	80 Units/1 Ml, 1 Time Weekly (Sunday)	Mallinckrodt
	Repository Corticotropin Injection	S	Unknown	40 Units/1 Ml	Mallinckrodt
	Repository Corticotropin Injection	S	Subcutaneous	40 Units/0.5 Ml, 1 Time Weekly (Sunday)	Mallinckrodt
	Repository Corticotropin Injection	S	Subcutaneous	40 Units / 0.5 Ml, 1 Time Weekly, Sunday	Mallinckrodt
	Repository Corticotropin Injection	S	Subcutaneous	80 Units / 1 Ml, 1 Time Weekly, Sunday	Mallinckrodt
	Repository Corticotropin Injection	S	Subcutaneous	40 Units Once Weekly	Mallinckrodt
	Plaquenil	S	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	5 Mg, Unk	Not Reported
	Prednisone	C	Unknown	Unk, Every Other Day	Not Reported
	Prednisone	C	Unknown	Unk, Once A Day	Not Reported
	Cellcept	C	Unknown	Unk	Not Reported
	Benlysta	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	16561502	EXPEDITED (15-DAY)		OT	CA-ROCHE-2351627		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective;	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Scoliosis; Spinal Disorder; Spinal Stenosis; Swelling; Therapeutic Response Decreased	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	16617646	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20190717471		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Chills; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Headache; Hepatic Enzyme Increased; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Joint Swelling; Liver Disorder;	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Loss Of Personal Independence In Daily Activities; Mesenteritis; Nausea; Oedema Peripheral; Off Label Use; Panniculitis; Peripheral Swelling; Pyrexia; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Alendronate Sodium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17121205	EXPEDITED (15-DAY)		OT	US-UCBSA-2017020170			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Pruritus; Rash; Rheumatoid Arthritis	Cimzia			S		Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Weekly (Qw)		Not Reported
	Enbrel			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Folic Acid			C	Oral	3 Mg, Once Daily (Qd)		Not Reported

	Nexium	C	Oral	20 Mg Daily	Not Reported
	Tofacitinib	C	Oral	11 Mg, Once Daily (Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17183725	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019543728			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Diabetes Mellitus; Drug Ineffective; Flank Pain; Lymphoma; Neutrophil Count Increased; Splenomegaly; White Blood Cell Count Increased; White Blood Cell Disorder	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Cortisone			C	Intramuscular	Unk, As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17245688	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512708		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine Phosphate	S	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17260299	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516104			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous bolus	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Etanercept	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17266000	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2516492		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	365		Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Pain; Pemphigus; Pericarditis; Pregnancy; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Cutaneous		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	365	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Prednisone	S	Oral	365.0	Not Reported

Prednisone	S	Unknown		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral	365.0	Not Reported
Sulfasalazine	S	Oral	365.0	Not Reported
Sulfathalidine	S	Unknown		Not Reported
Tofacitinib Citrate	S	Unknown		Not Reported
Topicort [Desoximetasone]	S	Cutaneous		Not Reported
Actemra	S	Unknown		Not Reported
Sarilumab	S	Unknown		Not Reported
Hydrocortisone Acetate	S	Subcutaneous		Not Reported
Hydrocortisone Acetate	S	Cutaneous		Not Reported
Paracetamol	S	Unknown		Not Reported
Cortisone	S	Oral		Not Reported
Xeljanz	S	Unknown		Not Reported
Salazopyrin	C			Not Reported
Leflunomide	C	Unknown		Not Reported
Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17336937	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530816			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Prefilled		Not Reported

			Syringe	
	Desoximetasone	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17370571	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2533713			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported

Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Kineret	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Naproxen	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Immunoglobulin Human Normal	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17397440	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050946		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Prescribed Underdose; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S		100 Mg, Unk		Not Reported
	Celebrex			S		200 Milligram		Not Reported
	Celebrex			S				Not Reported
	Celebrex			S		Unk		Not Reported
	Celebrex			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	1 Ml, Weekly (Qw)		Not Reported
	Plaquenil			S				Not Reported
	Apo-Prednisone			S		7 Mg, Once Daily (Qd)		Not Reported
	Apo-Leflunomide			S	Oral	10 Milligram, Once Daily (Qd)		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Once Daily		Not Reported

			(Qd)	
Remicade	S	Intravenous (not otherwise specified)	7 Milligram, Once Daily (Qd); Powder For Solution Intravenous	Not Reported
Simponi	S	Subcutaneous	Solution	Not Reported
Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
Hydroxychloroquine	S		300 Milligram, Once Daily (Qd)	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Sulfasalazine	S		500 Milligram	Not Reported
Apo-Azathioprine	S		Unk	Not Reported
Arava	S			Not Reported
Prednisone	S		7 Milligram, Once Daily (Qd)	Not Reported
Hydroxychloroquine Sulfate	S			Not Reported
Orencia	S	Intravenous (not otherwise specified)	0.75 Milligram, Monthly (Qm)	Not Reported
Celecoxib	S		Unk	Not Reported
Celecoxib	S		Unk	Not Reported
Azathioprine	S		Unk	Not Reported
Azathioprine	S		Unk	Not Reported
Acetaminophen And Codeine Phosphate	C		Unk	Not Reported
Altace	C		5 Milligram	Not Reported
Altace	C		10 Milligram	Not Reported
Apo-Gabapentin	C	Oral	100 Milligram	Not Reported
Apo-Gabapentin	C		300 Milligram	Not Reported
Atorvastatin Calcium	C	Oral	40 Milligram, Once Daily (Qd)	Not Reported
Atorvastatin Calcium	C		40 Milligram, Once Daily (Qd)	Not Reported
Cipralex [Escitalopram]	C		Unk	Not Reported

Hydromorphone Hcl	C	Oral	30 Milligram, 2x/Day (Bid)		Not Reported
Mupirocin	C	Topical	Unk		Not Reported
Pantoloc [Pantoprazole]	C		20 Milligram, Once Daily (Qd)		Not Reported
Shark Liver Oil	C		Unk		Not Reported
Tapentadol Hydrochloride	C		50 Milligram		Not Reported
Taro-Mupirocin	C	Topical	Unk		Not Reported
Tramacet	C	Oral			Not Reported
Tramadol Hydrochloride	C	Oral	50 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17454584	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555257		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Stress	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Advil [Ibuprofen]			C	Unknown			Not Reported

Prednisone	C	Oral	Not Reported
Prednisone	C	Oral	Not Reported
Tylenol	C	Unknown	Not Reported
Acetaminophen	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17457814	EXPEDITED (15-DAY)		HO	CA-UCBSA-2020007174		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Mycophenolate Mofetil			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Apo-Leflunomide			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Leflunomide			S		Unk		Not Reported
	Humira			C	Subcutaneous			Not Reported
	Celebrex			C				Not Reported
	Methotrexate			C		1 Milligram, Weekly (Qw)		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17464142	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553858			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Tooth Loss	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Zostavax	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Subcutaneous	Not Reported
	Cortisone Acetate	C	Subcutaneous	Not Reported
	Desoximetasone	C	Oral	Not Reported
	Diclofenac	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17567657	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022553		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50.0 Milligram		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tofacitinib Citrate	S	Oral	5.0 Milligram 2 Every 1 Days	Not Reported
	Xeljanz	S	Unknown	5.0 Milligram 2 Every 1 Days	Not Reported
	Aspirin [Acetylsalicylic Acid]	C	Unknown		Not Reported
	Cymbalta	C	Unknown		Not Reported
	Hydromorphone	C	Unknown		Not Reported
	Remicade	C	Intravenous (not otherwise specified)		Not Reported
	Synthroid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17578950	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024375			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2000 Milligram	Not Reported
	Synthroid	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Meloxicam	C	Unknown		Not Reported
	Acetaminophen;Codeine Phosphate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17601685	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003002044			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Abnormal; Burning Sensation; Constipation; Expired Product Administered; Gait Disturbance; Intentional Product Misuse; Malaise; Off Label Use; Paronychia; Skin Plaque; Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	2 Dosage Form, Bid (One In Morning And One In Evening, Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	3 Dosage Form (Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Amoxlcillin Trihydrate/Potassium Clavulanate			S	Unknown	Unk		Not Reported
	Amoxlcillin Trihydrate/Potassium Clavulanate			S				Not Reported
	Amoxlcillin Trihydrate/Potassium Clavulanate			S				Not Reported
	Lercan			C		10 Mg		Not Reported
	Quinine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17614338	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009150			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Levofloxacin	S	Unknown	Unk	Apotex
	Azithromycin	S	Unknown	250 Mg, Qd	Apotex
	Arava	S	Unknown	Unk	Not Reported
	Benadryl /00000402/	S	Unknown	Unk	Not Reported
	Celebrex	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Demerol	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Imuran /00001501/	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Pms Azithromycin	S	Unknown	250 Mg, Qd	Not Reported
	Procytox	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Procytox	S	Unknown	2000 Mg, Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Ezetrol	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17648477	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-VALIDUS PHARMACEUTICALS LLC-SK-2020VAL000270			Unknown	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction	Metoprolol Tartrate			S	Transplacental	Unk		Validus
	Cefotaxime Sodium			S	Transplacental	Unk		Validus

Cefotaxime Sodium	S	Transplacental	Unk	Validus
Dexamethasone	S	Transplacental	Unk	Not Reported
Dexamethasone	S	Transplacental	Unk	Not Reported
Cefixime	S	Transplacental	Unk	Not Reported
Prednisone	S	Transplacental	Unk	Not Reported
Prednisone	S	Transplacental	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Transplacental	Unk	Not Reported
Paracetamol	S	Transplacental	Unk	Not Reported
Methylprednisolone	S	Transplacental	Unk	Not Reported
Methylprednisolone	S	Transplacental	Unk	Not Reported
Omeprazole	S	Transplacental	Unk	Not Reported
Magnesium Lactate	S	Transplacental	Unk	Not Reported
Calcium Carbonate	S	Transplacental	Unk	Not Reported
Bisoprolol Fumarate	S	Transplacental	Unk	Not Reported
Fluconazole	S	Transplacental	Unk	Not Reported
Hydrocortisone	S	Transplacental	Unk	Not Reported
Potassium Chloride	S	Transplacental	Unk	Not Reported
Benzylpenicillin Sodium	S	Transplacental	Unk	Not Reported
Colecalciferol	S	Transplacental	Unk	Not Reported
Cefazolin Sodium	S	Transplacental	Unk	Not Reported
Albumin (Human)	S	Transplacental	Unk	Not Reported
Vitamin B Complex	S	Transplacental	Unk	Not Reported
Aminomethylbenzoic Acid	S	Transplacental	Unk	Not Reported
Flebogamma Dif /00025201/	S	Transplacental	Unk	Not Reported
Privigen	S	Transplacental	Unk	Not Reported
Privigen	S	Transplacental	Unk	Not Reported
Bisulepin	S	Transplacental	Unk	Not Reported
Folic Acid	S	Transplacental	Unk	Not Reported
Etamsylate	S	Transplacental	Unk	Not Reported

Nadroparine	S	Transplacental	Unk		Not Reported
Ornidazole	S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17706132	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20160600414			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17717838	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589516			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Spinal Compression Fracture	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17767050	EXPEDITED (15-DAY)		HO, LT, OT	JP-FERRINGPH-2020FE02993		41 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Disorder; Exposure During Pregnancy; Hormone Level Abnormal; Hypogonadism; Infarction; Pelvic Infection; Placenta Accreta; Pre-Eclampsia; Vaginal Haemorrhage	Lutinus			S	Vaginal	300 Mg, Daily		Ferring
	Estradiol			S	Transdermal			Not Reported
	Tacrolimus Monohydrate			S	Unknown	4 Mg		Not Reported
	Dydrogesterone			S	Oral	15 Mg, 1 Time Daily		Not Reported
	Prednisolone			S	Unknown	7.5 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17769919	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596223			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17770941	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591746		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Vaginal	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Not Reported
Xeljanz	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Acetaminophen	C		Not Reported
Anakinra	C	Unknown	Not Reported
Anakinra	C	Unknown	Not Reported
Ativan	C	Unknown	Not Reported
Ativan	C	Unknown	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C		Not Reported
Codeine	C		Not Reported
Cortisone	C	Intramuscular	Not Reported
Cortisone	C	Oral	Not Reported
Darifenacin Hydrobromide	C	Unknown	Not Reported
Darifenacin Hydrobromide	C	Oral	Not Reported
Desoximetasone	C	Intramuscular	Not Reported
Desoximetasone	C	Intra-articular	Not Reported
Desoximetasone	C	Intramuscular	Not Reported
Desoximetasone	C	Oral	Not Reported
Dilaudid	C		Not Reported
Diphenhydramine	C		Not Reported
Dexmethasone	C		Not Reported

	Dilaudid	C		Not Reported
	Diphenhydramine	C		Not Reported
	Diphenhydramine Hydrochloride	C	Unknown	Not Reported
	Dyclone	C		Not Reported
	Furosemide	C		Not Reported
	Hydromorphone	C		Not Reported
	Kadian	C		Not Reported
	Kenalog [Triamcinolone Acetonide]	C		Not Reported
	Lasix [Furosemide]	C		Not Reported
	Leflunomide	C		Not Reported
	Loperamide	C		Not Reported
	Morphine Sulfate	C		Not Reported
	Norflex [Orphenadrine Citrate]	C		Not Reported
	Omnaris	C		Not Reported
	Orencia	C		Not Reported
	Orphenadrine	C		Not Reported
	Orphenadrine Citrate	C		Not Reported
	Oxyneo	C		Not Reported
	Pantoloc [Pantoprazole]	C		Not Reported
	Pantoprazole	C		Not Reported
	Pantoprazole Sodium Anhydrous	C		Not Reported
	Plantago Ovata	C		Not Reported
	Restasis	C		Not Reported
	Sodium Aurothiomalate	C		Not Reported
	Synthroid	C		Not Reported
	Triamcinolone Acetonide	C		Not Reported
	Trimethoprim	C		Not Reported
	Urispas	C		Not Reported
	Vagifem	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17806211	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599022			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Perforation; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17816647	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200514277			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Nausea	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17817135	EXPEDITED (15-DAY)		DE	ES-PFIZER INC-2020202096		82 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
	Dolquine			S	Oral	400 Mg		Not Reported
	Kaletra E M			S	Oral	2 Df, 2x/Day (Each 12h)		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, 1x/Day		Not Reported
	Enalapril/Hydrochlorothiazide			C	Oral			Not Reported

	Omeprazole	C	Oral	20 Mg, 2x/Day (Each 12h)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17835075	EXPEDITED (15-DAY)		DE, OT	BR-PFIZER INC-2020204780		73 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Electrocardiogram Qt Prolonged; Off Label Use; Potentiating Drug Interaction; Product Use In Unapproved Indication	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
	Reuquinol			S		400 Mg, 2x/Day Every 12 Hours Before Sleep		Not Reported
	Reuquinol			S		400 Mg, 1x/Day		Not Reported
	Oseltamivir			C		75 Mg, 2x/Day		Not Reported
	Oseltamivir			C		75 Mg, 1x/Day		Not Reported
	Tazocin			C	Intravenous (not otherwise specified)	4.5 G, 4x/Day Every 6 Hours		Not Reported
	Tazocin			C	Intravenous (not otherwise specified)	4.5 G, 3x/Day Every 8 Hours		Not Reported
	Sodium Bicarbonate			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Bromoprida			C	Intravenous (not otherwise specified)	10 Mg, 3x/Day Every 8 Hours		Not Reported
	Potassium Chloride			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Chloride			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Cortisonal [Hydrocortisone]			C	Intravenous (not otherwise specified)	100 Mg, 2x/Day Every 12 Hours		Not Reported
	Dormire [Midazolam Hydrochloride]			C	Intravenous (not otherwise specified)	100 Mg, As Needed		Not Reported
	Encrise			C	Intravenous (not otherwise specified)	20 Iu, As Needed		Not Reported
	Fentanest [Fentanyl Citrate]			C	Intravenous (not otherwise specified)	2500 Ug, As Needed		Not Reported

	Norepinefrine	C	Intravenous (not otherwise specified)	32 Mg, As Needed	Not Reported
	Hemofol	C	Subcutaneous	5000 Iu, 2x/Day (Every 12 Hours)	Not Reported
	Hepamax S	C		Unk	Not Reported
	Novalgina	C	Intravenous (not otherwise specified)	1 G, As Needed	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17840976	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1240829		77 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Injury; Off Label Use; Pruritus; Purpura; Rash	Azithromycin			S	Oral	1 Dosage Forms		Not Reported
	Plaquenil			S	Oral	400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17843980	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP011163		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency;	Amlodipine			S	Oral	5 Mg, Qd		Apotex
	Amlodipine			S	Oral	Unk, Qd		Apotex
	Gliclazide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Apotex
	Asacol			S	Unknown	800 Mg, Tid		Not Reported
	Diamicron			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

Weight Increased	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Acetaminophen	C	Oral	650 Mg, Unk	Not Reported
	Amlodipine Besilate	C	Unknown	Unk	Not Reported
	Atacand Plus	C	Unknown	Unk	Not Reported
	Bisoprolol Fumarate	C	Unknown	Unk	Not Reported
	Crestor	C	Unknown	Unk	Not Reported
	Depo-Medrol	C	Intra-articular	Unk	Not Reported
	Diphenhydramine	C	Oral	50.0 Mg, Unk	Not Reported
	Ebastine	C	Unknown	Unk	Not Reported
	Ferrous Gluconate	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Mg, Unk	Not Reported
	Tylenol /00020001/	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844014	EXPEDITED (15-DAY)		HO	CA-ROCHE-2606464		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Hepatic Enzyme Increased; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Osteoarthritis; Pneumonia; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Zinc Citrate	C	Unknown	Not Reported
	Atorvastatin	C	Unknown	Not Reported
	Atorvastatin Calcium	C	Unknown	Not Reported
	Bisoprolol	C	Unknown	Not Reported
	Digoxin	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Furosemide Sodium	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Nifedipine	C	Unknown	Not Reported

Palafer	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Tocilizumab	C	Unknown	Not Reported
Toloxin [Digoxin]	C	Unknown	Not Reported
Trazodone	C	Unknown	Not Reported
Valsartan	C	Unknown	Not Reported
Vitamin D3	C	Unknown	Not Reported
Xarelto	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844059	EXPEDITED (15-DAY)		HO	CA-ROCHE-2609912		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Discomfort; Rash	Cefazolin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844091	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042281			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844304	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605582			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Infection; Inflammation; Interstitial Lung Disease; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Duration: 631.0 Days		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Duration: 631.0 Days		Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Duration: 631.0 Days	Not Reported
	Hydroxychloroquine	S			Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Duration: 631.0 Days	Not Reported
	Leflunomide	S	Oral	Duration: 631.0 Days	Not Reported
	Leflunomide	S			Not Reported
	Methotrexate	S	Unknown	Duration: 631.0 Days	Not Reported
	Naproxen	S	Unknown	Duration: 631.0 Days	Not Reported
	Naproxen	S	Unknown	Duration: 631.0 Days	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Duration 7 Yaers	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844330	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042253			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities	Orencia			S	Unknown			Bristol Myers Squibb
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

	Prednisone	C	Unknown	2 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844331	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-248768		42 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Azithromycin			S	Oral	250 Milligram, Daily		Sun
	Hydroxyzine			S	Intravenous (not otherwise specified)	25 Milligram, Qid		Not Reported
	Plaquenil 200 Mg, Comprime Enrobe			S	Oral	200 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844526	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606128		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Off Label Use; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	3.0 Years		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844569	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606231		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Golimumab	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Salazopyrin	C	Unknown	Not Reported
	Diclofenac	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844590	EXPEDITED (15-DAY)		DS	CA-ROCHE-2606292		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S	Unknown			Not Reported
	Aleve			C				Not Reported
	Arava			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported

	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844598	EXPEDITED (15-DAY)		OT	CA-ROCHE-2604929		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Animal Bite; Drug Ineffective; Emotional Disorder; Herpes Zoster; Inappropriate Schedule Of Product Administration; Malignant Melanoma; Mobility Decreased; Product Dose Omission; Victim Of Crime	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Restasis			C	Unknown			Not Reported
	Sulfasalazine			C	Oral			Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844794	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609327		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Body Height Decreased; Drug Ineffective; Flushing; Inflammation; Intentional Product Use Issue	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Simponi	S	Intravenous (not otherwise specified)	Not Reported
Xeljanz	S	Unknown	Not Reported
Acetaminophen	C	Unknown	Not Reported
Esomeprazole	C	Unknown	Not Reported
Esomeprazole Sodium	C	Unknown	Not Reported
Lumigan Rc	C	Ophthalmic	Not Reported
Lyrica	C	Unknown	Not Reported
Sulfasalazin	C	Unknown	Not Reported
Pseudoephedrine Hydrochloride	C	Unknown	Not Reported
Trazodone	C	Unknown	Not Reported
Valsartan	C	Unknown	Not Reported
Wellbutrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844809	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2020021835		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Depressed Mood; Disability; Hand Deformity; Inappropriate Schedule Of Product Administration; Inflammation; Limb Discomfort; Maternal Exposure During Pregnancy; Memory Impairment; Movement Disorder; Musculoskeletal Stiffness; Nasopharyngitis; Peripheral Swelling	Cimzia			S	Subcutaneous	Unk		Not Reported
	Azathioprine			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S				Not Reported
	Acetaminophen			C				Not Reported
	Amitriptyline			C		10 Milligram, Once Daily (Qd)		Not Reported
	Azithromycin			C				Not Reported
	Domperidone			C		3 Dosage Form		Not Reported
	Esomeprazole Sodium			C		20 Milligram		Not Reported
	Gabapentin			C		400 Milligram, Once Daily (Qd)		Not Reported
	Metonia			C		5 Milligram		Not Reported
	Prednisone			C		8 Milligram, Once Daily		Not Reported

				(Qd)		
	Ranitidine	C		Unk		Not Reported
	Xeljanz	C	Oral	5 Milligram, Once Daily (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844813	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606377			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Topical			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sulfasalazine		S	Unknown	Not Reported
	Topicort [Desoximetasone]		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844865	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606554			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844869	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606387		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Sciatica	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Ramipril			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844876	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608720		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder; Therapy Partial Responder	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Orencia	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Risedronate Sodium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844893	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605361			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Off Label Use; Rheumatoid Arthritis; Soft Tissue Swelling	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844913	EXPEDITED (15-DAY)		OT	CA-ROCHE-2610701		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Hydroxychloroquine Phosphate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844947	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2020-02444		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Dry Skin; Sexual Dysfunction	Triamcinolone Acetonide			S		5 Milligram Per Millilitre,		Lupin

				Every 6 To 8 Weeks	
	Triamcinolone Acetonide	S			Lupin
	Finasteride	S	Oral	1.25 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Lupin
	Isotretinoin	S	Oral	30 Milligram, Qd	Not Reported
	Isotretinoin	S	Topical	30 Milligram, Qod	Not Reported
	Tacrolimus	C	Topical	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844977	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606882			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Risedronate Sodium	S	Oral	Not Reported
	Risedronic Acid	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Risedronate Sodium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845025	EXPEDITED (15-DAY)		HO	CA-ROCHE-2609928			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845029	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609758			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845030	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609836			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis; Synovitis	Rituximab			S	Unknown	3.0 Years		Not Reported
	Enbrel			S	Unknown	260.0 Days		Not Reported
	Humira			S	Subcutaneous	346.0 Days		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	9.0 Years		Not Reported
	Methotrexate			S	Unknown	2040.0 Days		Not Reported
	Remicade			S	Unknown	2.0 Years		Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	2.0 Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845067	EXPEDITED (15-DAY)		HO	CA-ROCHE-2610757			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845119	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606900			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Solution For Injection In Pre-Filled Pen	Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845121	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606664		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Dorzolamide Hydrochloride;Timolol Maleate			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Estradiol			C	Unknown			Not Reported
	Estrogel			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Gravol			C				Not Reported

Potassium Chloride	C	Unknown	Not Reported
Valsartan	C	Unknown	Not Reported
Xalatan	C	Ophthalmic	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845122	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020021834			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug-Induced Liver Injury; Headache	Cimzia			S	Subcutaneous	200 Milligram, Ev 2 Weeks(Qow)		Not Reported
	Azathioprine			S		150 Milligram, Once Daily (Qd)		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Weekly (Qw)		Not Reported
	Methotrexate			C	Subcutaneous	15 Milligram, Weekly (Qw)		Not Reported
	Sulfasalazine			C		500 Milligram, 2x/Day (Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845152	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606067		80 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Sulfasalazine	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Allopurinol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845179	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1241649		79 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Erythema; Rash Pustular	Darunavir			S	Oral	800mg		Teva
	Ritonavir Sandoz			S	Oral	1 Dosage Form		Not Reported
	Plaquenil			S	Oral	2 Dosage Form		Not Reported
	Arixtra 2.5 Mg/0.5 Ml Solution For Injection Pre-Filled Syringe			C	Subcutaneous	1 Dosage Form		Not Reported
	Clexane			C	Subcutaneous	1 Dosage Form		Not Reported
	Folina 5 Mg Capsule Molli			C				Not Reported
	Medrol 16 Mg Compresse			C				Not Reported
	Tazocin 4 G/0,5 G Polvere Per Soluzione Per Infusione			C	Intravenous (not otherwise specified)	1 Dosage Form		Not Reported
	Kineret			C	Intravenous (not otherwise specified)	4 Dosage Forms		Not Reported
	Dibase 10.000 U.I./Ml Gocce Orali, Soluzione			C				Not Reported
	Azitromicina Teva 500 Mg Compresse Rivestite Con Film			C	Oral	1 Dosage Form		Not Reported
	Omeprazole Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845189	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609143		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective For	Rituximab			S	Intravenous drip			Not Reported
	Etanercept			S	Subcutaneous			Not Reported

Unapproved Indication; Hypersensitivity; Incorrect Route Of Product Administration; Laryngeal Disorder; Nausea; Pruritus; Treatment Failure; Weight Decreased	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Varicella-Zoster Immune Globulin	S	Subcutaneous	Not Reported
	Varicella-Zoster Immune Globulin	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845263	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609821			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Drug Ineffective; Joint Swelling	Rituximab			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Amitriptyline			C				Not Reported
	Cefazolin			C				Not Reported
	Clindamycin			C				Not Reported
	Prednisone			C	Unknown			Not Reported
	Tylenol With Codeine No.3			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845264	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609745			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Rheumatoid Arthritis	Rituximab	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845290	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605381		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Nasopharyngitis; Neutropenia; Off Label Use; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845339	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609611		30 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Gait Inability; Movement Disorder; Nausea; Pain; Weight Increased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845432	EXPEDITED (15-DAY)		OT	CA-ROCHE-2611697			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Rheumatoid Nodule; Treatment Failure	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845467	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606980			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Actemra			S	Unknown			Not Reported

Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Rituxan	S	Intravenous drip	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845521	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-02514		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Premature Delivery	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Prednisone			S	Unknown	Unk		Not Reported
	Insulin			S	Unknown	Unk		Not Reported
	Aspirine			S	Unknown	Unk		Not Reported
	Nifedipine			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Magnesium			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845639	EXPEDITED (15-DAY)		OT	CA-ROCHE-2607143			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Off Label Use; Product Use Issue; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown	Therapy Duration: 1460.0 Days		Not Reported
	Azathioprine			S	Oral			Not Reported
	Depo-Medrol With Lidocaine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 187.0 Days		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Ketoprofen			S	Topical			Not Reported
	Leucovorin Calcium			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prevnar 13			S	Intramuscular	Therapy Duration: 1.0 Days		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845687	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242647		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity;	Mycophenolate Mofetil			S	Unknown			Teva

Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Lyrica	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845790	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606657			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845826	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606204		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Impaired Work Ability; Nasopharyngitis; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Vioxx			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

	Wellbutrin	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845902	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US-001724			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Intentional Overdose	Hydroxychloroquine			S	Oral	Approximately 10-11 Gram		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845914	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1241289		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Hidroxicloroquina			S		200 Mg		Teva
	Azitromicina			S		500 Mg		Not Reported
	Kaletra			S		1 Dosage Form		Not Reported
	Interferon Beta			S		250 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845932	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2020-02532			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia Neonatal; Bronchopulmonary Dysplasia; Failure To Thrive; Fat Tissue Increased; Foetal Exposure During	Hydroxychloroquine			S	Transplacental	Unk		Lupin
	Sildenafil			S	Unknown	1 Milligram/Kilogram, Tid		Lupin
	Prednisone			S	Transplacental	Unk		Not Reported
	Insulin			S	Transplacental	Unk		Not Reported

Pregnancy; Foetal Growth Restriction; Haemangioma; Infantile Apnoea; Postnatal Growth Restriction; Premature Baby; Pulmonary Hypertension; Retinopathy Of Prematurity	Aspirine	S	Transplacental	Unk	Not Reported
	Nifedipine	S	Transplacental	Unk	Not Reported
	Magnesium	S	Transplacental	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845945	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608779			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17845972	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1241448		88 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846128	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1241996		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cough; Drug Intolerance; Dyspnoea; Forced Vital Capacity Decreased; Lung Diffusion Test Decreased; Pulmonary Function Test Decreased; Therapy Non-Responder; Treatment Failure	Mycophenolate Mofetil			S	Unknown	1440 Milligram Daily;		Teva
	Mycophenolate Mofetil			S	Oral			Teva
	Cyclophosphamide			S	Unknown	150 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Cymbalta			C	Unknown			Not Reported
	Domperidone			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846163	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606404		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Gait Disturbance; Nerve Compression	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Therapy Duration: 5.0 Years		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	Therapy Duration: 8.0 Years		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846172	EXPEDITED (15-DAY)		DE, OT	ES-ACCORD-183691		86 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Off Label Use	Hydroxychloroquine			S				Not Reported
	Kaletra			S				Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846174	EXPEDITED (15-DAY)		OT	AU-ROCHE-2611142			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Graft Versus Host Disease In Skin	Mabthera			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ibrutinib			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Sirolimus			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lamotrigine			C	Unknown			Not Reported
	Quetiapine			C				Not Reported
	Bactrim Ds			C				Not Reported
	Valaciclovir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846261	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242759		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

				otherwise specified)	
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846323	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606798			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax Plus D Cal			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846332	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605494		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Abdominal Pain; Alopecia; Arthropathy; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Glossodynia; Hand Deformity; Nausea; Oedema; Off Label Use; Pain; Pemphigus; Prescribed Overdose; Rheumatoid Arthritis; Synovitis; Systemic Lupus Erythematosus; Vomiting	Actemra	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846344	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606618			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Breast Cancer Female; Condition Aggravated; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846438	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1241766		57 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Piperacilina Tazobactam			S	Intravenous (not otherwise specified)	1 Amp/8h		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846439	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1241777		81 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatic Encephalopathy; Pancytopenia	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Amoxicilina Clavulanico			S	Intravenous (not otherwise specified)	1 Gr Every 12 Hours X 5 Days Followed By 1gr		Not Reported

Every 8 Hours X 6 Days

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846467	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606512		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Product Use Issue; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Risedronate Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846492	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609048		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Rheumatoid Arthritis; Treatment Failure	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846572	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020212010		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Azithromycin			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846584	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608772			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846599	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605656		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased;	Actemra			S	Unknown			Not Reported
	Allopurinol			S	Unknown			Not Reported

Condition Aggravated; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Product Complaint; Rash; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Amitriptyline	S	Unknown	Not Reported
	Amitriptyline	S	Unknown	Not Reported
	Amitriptyline Hydrochloride;Perphenazine	S	Unknown	Not Reported
	Apo-Amitriptyline	S	Unknown	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Apo-Diclofenac	S	Topical	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Naproxen	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Celebrex	S		Not Reported
	Celecoxib	S	Unknown	Not Reported
	Celecoxib	S		Not Reported
	Diclofenac	S	Unknown	Not Reported
	Diclofenac Potassium	S	Unknown	Not Reported
	Diclofenac Sodium/Misoprostol	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Etanercept	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Parenteral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported

	Methotrexate	S	Subcutaneous	Not Reported
	Misoprostol	S	Unknown	Not Reported
	Naprosyn [Naproxen]	S	Unknown	Not Reported
	Naproxen	S	Unknown	Not Reported
	Nifedipine	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pregabalin	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Winpred	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846772	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1241463		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hypertransaminasaemia; Long Qt Syndrome	Azitromicina (7019a)			S	Oral	500 Milligram		Not Reported
	Hidroxicloroquina 200 Mg Comprimido			S		200 Milligram		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846790	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606913			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fibrosis; Ill-Defined Disorder; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Actemra			S	Unknown			Not Reported
	Etanercept			S	Unknown	2190.0 Days		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846996	EXPEDITED (15-DAY)		OT	CA-ROCHE-2607028			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846998	EXPEDITED (15-DAY)		OT	NL-PFIZER INC-2020212284			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Haemolytic Anaemia	Etanercept	S	Unk	Pfizer
	Sulfasalazine	S	Unk	Pfizer
	Methotrexate	S	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847019	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606601		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Salazopyrine	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847045	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020211935		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Repolarisation Abnormality; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported
	Rocephine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847047	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2020212312		11 YR	Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Infection; Off Label Use; Product Use In Unapproved Indication; Shock	Azithromycin			S	Unknown	Unk		Pfizer
	Methylprednisolone Sodium Succinate			S	Unknown	Unk		Pfizer
	Lopinavir/Ritonavir			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847132	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020211145			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Meningitis; Pain; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847143	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606599			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847178	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606680			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847192	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606635		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847247	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608755			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis	Rituximab			S	Unknown	Therapy Duration:3.0 Years		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 9.0 Months		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 346.0 Days		Not Reported
	Hydroxychloroquine			S	Unknown	Therapy Duration: 9.0 Years		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 7.0 Years		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 2.0 Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847279	EXPEDITED (15-DAY)		CA	NVSC2020US148890			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia; Premature Baby	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Transplacental	Unk		Novartis

	Tacrolimus	S	Transplacental	Unk		Not Reported
	Prednisone	S	Transplacental	Unk		Not Reported
	Betamethasone	S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847317	EXPEDITED (15-DAY)		OT	CA-ROCHE-2607208		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847469	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-015776			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Exposure During Pregnancy; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cortisone Acetate			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847581	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606548		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Urethral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847583	EXPEDITED (15-DAY)		OT	US-009507513-2005USA008649			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphocytopenia Neonatal	Celestone Soluspan			S		Unk		Merck
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Tacrolimus			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847587	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608166			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angiopathy; Panniculitis	Mycophenolate Mofetil			S	Unknown			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Colchicine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847672	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606953		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Headache; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Viral Infection	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847685	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606636		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use; Synovitis	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Dorzolamide			C	Unknown			Not Reported

Hydrochloride;Timolol Maleate				
Ergocalciferol	C	Unknown		Not Reported
Estrogel	C	Unknown		Not Reported
Furosemide	C	Unknown		Not Reported
Morphine	C			Not Reported
Potassium Chloride	C	Unknown		Not Reported
Valsartan	C	Unknown		Not Reported
Xalatan	C	Unknown		Not Reported
Zingiber Officinale	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847686	NON-EXPEDITED			US-009507513-2006USA000273			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy	Celestone Soluspan			S		Unk		Merck
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Tacrolimus			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847700	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1242689		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Autoimmune Disorder; Cognitive Disorder; Cushing'S Syndrome; Headache; Infusion Related Reaction; Leukopenia; Muscular Weakness; Paralysis; Proteinuria; Psychotic	Mycophenolate Mofetil			S	Unknown			Teva
	Apo-Azathioprine			S	Unknown	100 Milligram Daily;		Not Reported
	Apo-Azathioprine			S	Unknown	50 Milligram Daily;		Not Reported
	Apo-Azathioprine			S	Unknown	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Procytox			S	Intravenous (not			Not Reported

Disorder; Therapeutic Response Decreased				otherwise specified)	
	Procytox		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous drip	Not Reported
	Rituximab		S		Not Reported
	Acetaminophen		C	Unknown	Not Reported
	Diphenhydramine Hydrochloride		C	Unknown	Not Reported
	Methylprednisolone		C	Unknown	Not Reported
	Methylprednisolone Sodium Succinate		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847704	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242753		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Piroxicam	C		Not Reported
Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847787	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042381			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	2.5 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Tenofovir Disoproxil Fumarate			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Zopiclone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847848	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540932		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthritis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Finger Deformity; Gait Disturbance; Therapeutic Product Effect Decreased	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17848194	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3205448-00		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Fibromyalgia; Lymphoedema; Obesity; Pneumocystis Jirovecii Pneumonia; Pulmonary Embolism	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Orencia	S	Unknown		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Xarelto	C			Not Reported
	Prednisone	C	Qd, Tapering		Not Reported
	Hydrocortisone	C			Not Reported
	Tylenol Arthritis	C			Not Reported
	Calcium Vitamin D	C			Not Reported
	Pantoloc	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	8644662	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-16703324		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Faeces Discoloured; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Joint Swelling; Knee Arthroplasty; Liver Function Test Abnormal; Malaise; Meniscus Injury; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Paraplegia; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid	Abatacept			S	Unknown	Inf:8,Last Infusion On 24-May-2012 Last Infusion On 15-Jan-2014. 3j75953-Exp Date:Jul-2016.		Bristol Myers Squibb
	Abatacept			S	Unknown			Bristol Myers Squibb
	Methotrexate Sodium			S	Unknown	1 Df, Qwk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Aclasta			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	400 Mg, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	2 G, A Day		Not Reported

Arthritis; Sleep Disorder; Spinal Disorder; Spinal Stenosis; Treatment Failure; Upper Respiratory Tract Infection	Tramacet	S	Unknown	Unk	Not Reported
	Tramacet	S	Oral	Unk	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Methotrexate	S	Unknown	1.75 Milligram	Not Reported
	Tramadol + Acetaminofen	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Oxycocet	C	Unknown		Not Reported
	Lyrica	C	Oral	150 Mg, Bid	Not Reported
	Amitriptyline	C	Unknown		Not Reported
	Nortriptyline	C	Unknown	2 Tab, Unk	Not Reported
	Nortriptyline	C	Unknown		Not Reported
	Depo-Medrol	C	Subcutaneous	Unk, Qmo	Not Reported
	Depo-Medrol	C	Intramuscular	Unk, Qmo	Not Reported
	Metformin	C	Unknown	500 Mg, Bid	Not Reported
	Metformin	C	Unknown	5 Milligram, Qd	Not Reported
	Lorazepam	C	Unknown	1 Milligram, Qd	Not Reported
	Vagifem	C	Unknown	Unk	Not Reported
	Premarin	C	Unknown	0.625 Milligram	Not Reported
	Vitamin D [Ergocalciferol]	C	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Tylenol Arthritis	C	Unknown	Unk, Q8h	Not Reported
	Actonel	C	Unknown	35 Milligram, Qwk	Not Reported
	Methylprednisolone Acetate	C	Unknown		Not Reported
	Methylprednisolone Acetate	C	Subcutaneous	Unk, Qmo	Not Reported
	Methylprednisolone Acetate	C	Subcutaneous	40 Milligram, Qmo	Not Reported
	Methylprednisolone Acetate	C	Intramuscular	40 Milligram, Qmo	Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Nortriptylin	C	Unknown	20 Milligram, Qd	Not Reported
	Nortriptylin	C	Unknown		Not Reported

	Risedronate Sodium	C	Unknown	35 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	12309292	EXPEDITED (15-DAY)		HO	CA-ROCHE-1746971			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Product Use Issue; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 6 Months		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 5 Months		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	Therapy Duration: 581 Days		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Therapy Duration: 581 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	12769954	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076679			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Movement Disorder; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Bid		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Rituxan			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			C	Oral	Unk		Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	12912801	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091708		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Oral	5 Milligram, Q12h		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Endocervical	400 Milligram		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone Acetate			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Folic Acid			C	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Phosphate			C	Unknown	Unk		Not Reported
	Insulin			C	Oral	Drops Oral		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported

	Acetaminophen And Codeine	C	Unknown		Not Reported
	Celebrex	C	Unknown	2 Dosage Form, Qd	Not Reported
	Metformin	C	Unknown	1 Dosage Form	Not Reported
	Metformin	C	Unknown	2 Dosage Form, Bid	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	20 Milligram	Not Reported
	Leflunomide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	12913692	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091875		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis; Therapeutic Response Decreased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Intracardiac	8 Milligram/Kilogram		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Rituximab;Vorhyaluronidase Alfa			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Hydroxychloroquine Sulphate			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Rituximab			S	Intravenous (not	1000 Milligram		Not Reported

			otherwise specified)		
Plaquenil [Hydroxychloroquine Phosphate]		C	Unknown	Unk	Not Reported
Premarin		C	Unknown	Unk	Not Reported
Tenormin		C	Unknown	Unk	Not Reported
Xeljanz		C	Unknown	Unk	Not Reported
Cymbalta		C	Unknown	Unk	Not Reported
Arava		C	Unknown	Unk	Not Reported
Calcium Carbonate		C	Unknown	Unk	Not Reported
Elavil [Amitriptyline Hydrochloride]		C	Unknown	Unk	Not Reported
Imitrex [Sumatriptan]		C	Unknown	Unk	Not Reported
Lyrica		C	Unknown	Unk	Not Reported
Hydrochlorothiazide		C	Unknown	Unk	Not Reported
Acetaminophen		C	Unknown	Unk	Not Reported
Sumatriptan Succinate		C	Unknown	Unk	Not Reported
Amitriptyline Hydrochloride		C	Unknown	Unk	Not Reported
Amitriptyline		C	Unknown		Not Reported
Sumatriptan		C	Unknown		Not Reported
Tofacitinib		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	13058525	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015728		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Apo-Azathioprine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Unknown	100 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Unk		Not Reported

	Enbrel	S	Subcutaneous	Unk Unk, Q.Wk.	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Imuran /00001501/	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	100 Mg, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Kineret	S	Unknown	100 Mg, Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	13286858	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1899556		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celecoxib			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 330.0 Day(S)		Not Reported

Gastrointestinal Disorder; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Oxycontin	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Celebrex	S	Oral	Not Reported
	Celebrex	S	Unknown	Not Reported
	Fentanyl Citrate	S	Epidural	Not Reported
	Fentanyl Matrix	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Nortriptyline Hydrochloride	S	Oral	Not Reported
	Nortriptyline Hydrochloride	S		Not Reported
	Nortriptyline Hydrochloride	S	Unknown	Not Reported
	Nortriptyline Hydrochloride	S		Not Reported
	Omega 3 Fish Oils	S	Unknown	Not Reported
	Orencia	S	Vaginal	Not Reported
	Orencia	S		Not Reported
	Xeljanz	S	Oral	Not Reported
	Thiamine Hydrochloride	S	Unknown	Not Reported
	Thiamine Hydrochloride	S	Unknown	Not Reported
	Vitamin B-1	S	Unknown	Not Reported
	Xeljanz	S	Endocervical	Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C	Unknown	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	Not Reported
	Aclasta	C	Intravenous (not	Not Reported

		otherwise specified)	
Aclasta	C	Intravenous (not otherwise specified)	Not Reported
Actonel	C	Unknown	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Esomeprazole	C	Unknown	Not Reported
Ferrous Gluconate	C	Unknown	Not Reported
Loperamide Hydrochloride	C	Unknown	Not Reported
Nasonex	C	Unknown	Not Reported
Pantoprazole Magnesium	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Trazodone Hydrochloride	C	Oral	Not Reported
Tylenol	C	Oral	Not Reported
Acetaminophen	C	Unknown	Not Reported
Apo-Gabapentin	C	Oral	Not Reported
Ascorbic Acid	C	Unknown	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	C	Unknown	Not Reported
Biotin	C	Unknown	Not Reported
Cholecalciferol	C	Unknown	Not Reported
D-Alpha Tocopherol	C	Unknown	Not Reported
D-Alpha Tocopheryl Acetate	C	Unknown	Not Reported
Diphenoxylate	C	Unknown	Not Reported
Diphenoxylate	C	Unknown	Not Reported
Docosahexaenoic Acid	C	Unknown	Not Reported

Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
Fergon	C	Unknown	Not Reported
Ferrous Fumarate	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown	Not Reported
Loperamide	C	Unknown	Not Reported
Esomeprazole	C	Unknown	Not Reported
Nicotinamide	C	Unknown	Not Reported
Perphenazine	C	Oral	Not Reported
Perphenazine	C	Unknown	Not Reported
Pyridoxine	C	Unknown	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Not Reported
Retinol Palmitate	C	Unknown	Not Reported
Riboflavin	C	Unknown	Not Reported
Sodium Ascorbate	C	Unknown	Not Reported
Tecta	C	Unknown	Not Reported
Thiamine Hydrochloride	C	Unknown	Not Reported
Thiamine Mononitrate	C	Unknown	Not Reported
Trazodone	C	Unknown	Not Reported
Vitamin B12 [Cyanocobalamin]	C		Not Reported
Vitamin D3	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	13659278	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170611422		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Reaction; Blood Iron	Remicade			S	Intravenous (not			Not Reported

Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure			otherwise specified)	
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Janssen
	Simponi	S		Janssen
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Cellcept	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Mycophenolate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Pregabalin	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Piroxicam	S	Unknown	Not Reported
	Actemra	S		Not Reported
	Actemra	S		Not Reported
	Actemra	S		Not Reported
	Azathioprine	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported

	Certolizumab Pegol	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Ciclosporin	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine /00072603/	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Imuran /00001501/	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Mycophenolate Mofetil	S		Not Reported
	Prednisone	C	Unknown	Not Reported
	Piroxicam	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	13984193	EXPEDITED (15-DAY)		OT	CA-ROCHE-1993146			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Synovitis; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 730 Nos		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Therapy Duration: 4 Years		Not Reported
	Meloxicam			C				Not Reported

	Sulfasalazine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	13988289	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-083265		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Tremor	Orencia			S	Unknown	40 Milligram, Q2wk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Oral	2.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	10.0 Milligram, Qwk		Not Reported
	Methotrexate			C	Oral	15.0 Milligram, Qwk		Not Reported
	Methotrexate			C	Oral	2.5 Milligram, Qwk		Not Reported

	Methotrexate	C	Unknown	1 Dosage Form, Qwk	Not Reported
	Folic Acid	C	Oral	2.5 Milligram, Qd	Not Reported
	Pantoprazole	C	Oral	40 Milligram, Qd	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Zopiclone	C	Unknown	7.5 Milligram, Qd	Not Reported
	Tenofovir Disoproxil Fumarate	C	Oral	300 Milligram	Not Reported
	Pantoprazole Sodium Sesquihydrate	C	Unknown	Unk	Not Reported
	Tenofovir Disoproxil	C	Unknown	Unk	Not Reported
	Tenofovir	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	300 Milligram	Not Reported
	Pantoprazole Sodium Anhydrous	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	14206623	EXPEDITED (15-DAY)		OT	CA-ROCHE-2025500		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Osteoarthritis; Rheumatoid Factor Positive; Synovitis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	14827888	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2110529		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 6.0 Month(S)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	6.0 Months		Not Reported
	Anakinra			S	Subcutaneous	3.0 Years		Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous	3.0 Years		Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Therapy Duaration: 3months		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Immune Globulin (Immunoglobulins Nos)			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

Triamcinolone	S	Other		Not Reported
Adalimumab	S	Subcutaneous	Therapy Duration: 3.0 Months	Not Reported
Adalimumab	S	Unknown		Not Reported
Apo-Naproxen	S	Unknown		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Triamcinolone Hexacetonide	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	14917666	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007162		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Tofacitinib Citrate			S	Oral	5.0 Mg, Unk		Not Reported

Aspirin [Acetylsalicylic Acid]	C	Unknown	Unk		Not Reported
Cymbalta	C	Unknown	Unk		Not Reported
Remicade	C	Intravenous (not otherwise specified)	Unk		Not Reported
Hydromorphone	C	Unknown	Unk		Not Reported
Synthroid	C	Unknown	Unk		Not Reported
Acetylsalicylic Acid	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	14923972	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044325			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Mirtazapine			S	Unknown	15 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	15422962	EXPEDITED (15-DAY)		OT	DE-ROCHE-2186283		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Failure	Rituxan	S	Intravenous drip		Not Reported
	Rituximab	S	Oral		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown	Solution Subcutaneous	Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
	Apo-Hydroxyquine	S	Oral	Unk	Not Reported
	Ciclosporin	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Neoral	S	Oral	Unk	Not Reported
	Neoral	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported

	Xeljanz		C	Oral	5 Mg Bid	Not Reported
	Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	15619727	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555831-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	15629381	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2558926-00		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Nodule; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

	Apo-Leflunomide	S	Unknown		Not Reported
	Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	15801087	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2617003-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S				Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Leucovorin			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Prednisone			S	Unknown	2 Dosage Forms		Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	15956472	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190209141		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Drug Reaction; Arthritis; Bone Erosion; C-Reactive Protein Increased; Crohn'S Disease; Decreased Appetite; Drug Ineffective; Drug Intolerance; Exostosis; Fatigue; Foot Deformity; Hepatic Cirrhosis; Hypoaesthesia; Joint Dislocation; Joint Stiffness; Malaise; Mobility Decreased; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Rash; Red Blood Cell Sedimentation Rate Increased; Retinitis; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure; Visual Impairment	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Janssen
	Stelara	S	Subcutaneous		Janssen
	Enbrel	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous	Single Use Pre Filled Syringe	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Otezla	S	Oral		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine /00072603/	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Certolizumab Pegol	S	Subcutaneous		Not Reported
	Etanercept	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Minocycline	S	Unknown		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Sirukumab	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not		Not Reported

			otherwise specified)	
	Apo-Leflunomide	S	Unknown	Not Reported
	Golimumab	S	Subcutaneous	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Bupropion Hydrochloride	C		Not Reported
	Hydromorphone Hydrochloride	C		Not Reported
	Bupropion	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	15978220	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013626			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	40 Milligram		Not Reported
	Rituximab			S	Intravenous (not	Unk		Not Reported

				otherwise specified)		
	Prednisone		C	Unknown	10 Milligram	Not Reported
	Cimzia		C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	16537770	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-063625		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Qmo		Bristol Myers Squibb
	Anakinra			S	Subcutaneous	100.0 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	20.0 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Millilitre Per Kilogram		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Xeljanz			C	Unknown	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	16884373	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201909000458			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Drug Ineffective; Dyspepsia; Frustration	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Alemtuzumab			S	Intravenous drip	12 Mg, Qd		Not Reported
	Tysabri			C				Not Reported

Tolerance Decreased; Hypersensitivity; Increased Tendency To Bruise; Joint Stiffness; Paraesthesia Oral; Rash	Copaxone	C		Not Reported
	Betaseron	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17146486	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191211370			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Liver Injury; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Psoriatic Arthropathy; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Reactine (Cetirizine Dihydrochloride)			S	Unknown			Johnson And Johnson
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Johnson And Johnson
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi Iv			S	Subcutaneous			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported

	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Etanercept	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Calcium /00060701/	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Quetiapine	C	Unknown	Not Reported
	Ramipril	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17157342	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053627			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Liver Injury; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Psoriatic Arthropathy; Rheumatoid Arthritis; Swelling; Systemic Lupus	Cimzia			S	Subcutaneous	Unk		Ucb
	Certolizumab Pegol			S	Subcutaneous	Unk		Ucb
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S		Unk		Not Reported

Erythematosus; Wound	Arava	S	Unknown		Not Reported
	Diclofenac Sodium	S			Not Reported
	Diclofenac Sodium	S		Unk	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Fosamax	S		Unk	Not Reported
	Fosamax	S	Unknown		Not Reported
	Folic Acid	S			Not Reported
	Folic Acid	S		1 Milligram	Not Reported
	Humira	S	Subcutaneous	Solution	Ucb
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Methotrexate	S		Solution	Not Reported
	Methotrexate	S		Unk	Not Reported
	Methotrexate	S		Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S			Not Reported
	Prednisone	S		Unk	Not Reported
	Prednisone	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Etanercept	S	Subcutaneous		Not Reported

	Etanercept	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Desoximetasone	S	Oral			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Cosentyx	S	Unknown			Not Reported
	Calcium /00060701/	C	Unknown			Not Reported
	Pantoprazole	C	Unknown			Not Reported
	Quetiapine	C	Unknown			Not Reported
	Ramipril	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17281615	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518250		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Endodontic Procedure; Flushing; Heart Rate Decreased; Herpes Zoster; Ill-Defined Disorder; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Anakinra	S	Unknown		Not Reported
	Etanercept	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Infliximab	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Naproxen	S	Unknown		Not Reported
	Kineret	S	Subcutaneous	Solution Subcutaneous, 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Acetaminophen	C			Not Reported
	Diphenhydramine Hydrochloride	C	Unknown		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Folic Acid	C			Not Reported
	Lasix [Furosemide]	C			Not Reported
	Methylprednisolone	C			Not Reported
	Naprosyn E	C			Not Reported
	Oxycontin	C	Unknown	Tablet (Extended Release)	Not Reported
	Oxyneo	C	Unknown	Tablet (Extended Release)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17351116	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530650		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic	Actemra			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Off Label Use; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Rituximab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Ciprofloxacin	S	Unknown	Not Reported
	Amoxicillin;Clavulanate Potassium	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Ciprofloxacin Hydrochloride	S	Unknown	Not Reported
	Amoxicillin Trihydrate;Clavulanate Potassium	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Amoxicillin Sodium;Clavulanate Potassium	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Tridural	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Cimetidine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17363386	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005934		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Orencia		S	Unknown	Unk	Bristol Myers Squibb
	Actemra		S	Unknown	Unk	Not Reported
	Apo-Leflunomide		S	Unknown	Unk	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Humira		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade		C	Intravenous (not otherwise specified)		Not Reported
	Prednisone		C	Unknown	5 Milligram, Qd	Not Reported
	Prednisone		C	Unknown	10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17364200	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533943		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blister; Confusional State; Contraindicated Product Administered; Contusion; Drug Ineffective; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Off Label Use; Peripheral Swelling; Pruritus; Pyrexia; Rash;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Chlorhexidine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Weight Increased			otherwise specified)	
	Oxycodone	S	Unknown	Not Reported
	Oxycodone Terephthalate	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown	Not Reported
	Periogard	S	Unknown	Not Reported
	Act Oxycodone Cr	S	Unknown	Not Reported
	Sulfamethoxazole	S	Unknown	Not Reported
	Oxycodone Hydrochloride	S	Unknown	Not Reported
	Chlorhexidine Gluconate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Acetaminophen;Oxycodone Hydrochloride	S	Unknown	Not Reported
	Arava	C	Oral	Not Reported
	Desogestrel;Ethinylestradiol	C		Not Reported
	Ibuprofen	C		Not Reported
	Pantoloc [Pantoprazole]	C		Not Reported
	Pantoprazole Sodium	C		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C		Not Reported
	Prednisone	C	Oral	Not Reported
	Reactine [Cetirizine Hydrochloride]	C		Not Reported
	Tylenol	C		Not Reported
	Hydroxychloroquine Sulfate	C		Not Reported
	Cetirizine Hydrochloride	C		Not Reported
	Pantoprazole	C		Not Reported
	Paracetamol	C		Not Reported
	Cetrizine	C	Unknown	Not Reported
	Hydroxychloroquine Phosphate	C	Unknown	Not Reported
	Paracetamol Codeine	C	Unknown	Not Reported
	Tylenol With Codeine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17399035	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-010345		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cannabis Sativa			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Oxycodone			S	Unknown	10 Milligram		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ilaris			C	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Rituximab			C	Unknown			Not Reported

	Lyrica		C	Oral		Not Reported
	Xeljanz		C	Oral	Unk, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17399645	EXPEDITED (15-DAY)		DS, HO, LT	CA-ROCHE-2538087		365 DAY	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Abatacept			S	Intravenous drip			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Naproxen			S				Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use Issue; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Short Stature; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5.0 Months	Not Reported
	Infliximab	S	Unknown	9.0 Months	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Kineret	S	Subcutaneous	3.0 Years, Kineret 100 Mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes	Not Reported
	Kineret	S	Subcutaneous		Not Reported
	Kineret	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	10.0 Years	Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	3.0 Months	Not Reported
	Orencia	S	Respiratory (inhalation)		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S			Not Reported
	Triamcinolone Acetonide	S	Intra-articular		Not Reported
	Triamcinolone Acetonide	S	Unknown		Not Reported
	Triamcinolone Acetonide	S	Oral		Not Reported
	Triamcinolone Acetonide	S			Not Reported

	Gamastan	S	Intramuscular	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Unknown	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S		Not Reported
	Folic Acid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17424444	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543750			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Bone Erosion; Contraindicated Product Administered; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Exostosis; Foot Deformity; Headache; Hepatic Cirrhosis; Infection; Joint Dislocation; Joint Stiffness; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Pneumonia; Synovitis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Intravenous (not			Not Reported

			otherwise specified)	
	Sirukumab	S	Unknown	Not Reported
	Stelara	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Morphine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Dilaudid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17486761	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202002001091			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acantholysis; Blister; Dermatitis; Herpes Zoster; Inflammation; Macule; Pain; Pruritus; Skin Plaque; Varicella Zoster Virus Infection	Hydroxychloroquine			S	Oral	100 Mg, Qd, Plaquenil Tablet		Concordia
	Prednisone			S	Unknown	40 Mg, Qd		Not Reported
	Prednisone			S	Unknown	35 Mg, Qd		Not Reported
	Prednisone			S	Unknown	30 Mg, Qd		Not Reported
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisone			S	Unknown	20 Mg, Qd, Tapering Dose		Not Reported
	Imuran			S	Oral	50 Mg, Qd		Not Reported

	Shingrix	S	Unknown	Unk,To Her Right Deltoid	Not Reported
	Calcium Carbonate	C		Unk	Not Reported
	Levothyroxine	C		Unk	Not Reported
	Ortho-Novum	C		Unk	Not Reported
	Zyrtec	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17535302	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566151		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Osteoarthritis; Rheumatoid Factor Positive; Synovitis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Simponi			C				Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17552428	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021329		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17561204	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021856		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell	Orencia			S	Unknown			Bristol Myers Squibb
	Acetaminophen			S	Unknown	325 Milligram		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram, 4 Every One Week		Not Reported

Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Enbrel	S	Unknown	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Q12h	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	200 Milligram	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Subcutaneous	2000 Milligram	Not Reported
	Leflunomide	S	Unknown	200 Milligram, Qd	Not Reported
	Tylenol	S	Unknown		Not Reported
	Acetaminophen;Diphenhydramine Hydrochloride	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, 1 Every 1 Days	Not Reported
	Codeine	C	Unknown		Not Reported
	Meloxicam	C	Unknown		Not Reported
	Methotrexate	C	Unknown	Unk, Qwk	Not Reported
	Synthroid	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported
	Hydromorphone Hydrochloride	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Celecoxib	C	Unknown	Unk	Not Reported
	Acetaminophen;Codeine Phosphate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17563694	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022541			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia	S	Unknown	Bristol Myers Squibb
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17687059	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-032291		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Musculoskeletal Discomfort; Pain; Pemphigus; Swelling; Systemic Lupus	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported

Erythematosus	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	400 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisolone	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17741749	EXPEDITED (15-DAY)		OT	CH-SA-2020SA114056			Unknown	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Plaquenil			S	Oral	In Total		Sanofi
	Amoxicillin Sodium/Potassium Clavulanate			S	Intravenous drip	1.2 G, Qid		Not Reported
	Lopinavir/Ritonavir			S	Oral	400 Mg, Bid		Not Reported
	Lopinavir/Ritonavir			S	Oral	400 Mg, Bid		Not Reported
	Clexane			S	Subcutaneous	40 Mg, Qd		Sanofi
	Clexane			S	Subcutaneous	40 Mg, Bid		Sanofi
	Clexane			S	Subcutaneous	Unk		Sanofi
	Clexane			S	Subcutaneous	40 Mg, Bid		Sanofi
	Paracetamol			S	Intravenous (not otherwise specified)	Max 3x/D ; As Necessary		Not Reported

Piperacillin/Tazobactam	S	Intravenous drip	4.5 G, Tid	Not Reported
Azithromycin	S	Oral	500 Mg, Qd	Not Reported
Ipramol	C		Unk	Not Reported
Temesta [Lorazepam]	C			Not Reported
Tavanic	C			Not Reported
Atracurium	C		Unk	Not Reported
Fentanyl	C		Unk	Not Reported
Dormicum [Midazolam Hydrochloride]	C		Unk	Not Reported
Phosphate [Potassium Bicarbonate;Sodium Phosphate Monobasic]	C		Unk	Not Reported
Antibiotics For Otic And Nasal Use	C		Unk	Not Reported
Torasemide	C			Not Reported
Potassium	C			Not Reported
Benerva	C			Not Reported
Heparin	C		Unk	Not Reported
Solu-Medrol	C		Unk	Not Reported
Novorapid	C		Unk	Not Reported
Relistor	C		Unk	Not Reported
Novasource Gi Control	C		Unk	Not Reported
Ventolin [Salbutamol]	C		Unk, Prn	Not Reported
Movicol [Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Ch	C		Unk, Prn	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17754585	EXPEDITED (15-DAY)		OT	CH-ABBVIE-20K-151-3387973-00		51 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Hepatic Artery Occlusion; Hepatic	Kaletra			S	Oral			Not Reported
	Kaletra			S	Oral			Not Reported

Infarction; Hepatocellular Injury; Hypoperfusion; Liver Function Test Increased; Off Label Use; Off Label Use	Augmentin	S	Intravenous drip		Not Reported
	Plaquenil	S	Oral		Not Reported
	Clexane	S	Subcutaneous		Not Reported
	Clexane	S	Subcutaneous		Not Reported
	Clexane	S	Subcutaneous		Not Reported
	Clexane	S	Subcutaneous		Not Reported
	Perfalgan	S	Intravenous (not otherwise specified)	Maximum 3 Times A Day	Not Reported
	Piperacilline/Tazobactam	S	Intravenous drip		Not Reported
	Zithromax	S	Oral		Not Reported
	Ipramol	C			Not Reported
	Temesta	C			Not Reported
	Tavanic	C			Not Reported
	Atracurium	C			Not Reported
	Fentanyl	C			Not Reported
	Dormicum	C			Not Reported
	Phosphate	C			Not Reported
	Colistin	C			Not Reported
	Torasemide	C			Not Reported
	Potassium Chloride	C			Not Reported
	Benerva	C			Not Reported
	Heparin	C			Not Reported
	Solu-Medrol	C			Not Reported
	Relistor	C			Not Reported
	Novasource Gi Control	C			Not Reported
	Ventolin	C			Not Reported
	Movicol	C			Not Reported
	Novorapid	C			Not Reported
	Tobramycin	C			Not Reported
	Amphotericin B	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17765937	EXPEDITED (15-DAY)		OT	CA-ROCHE-1748865		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive	Actemra			S	Unknown			Not Reported

Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fall; Fatigue; Femur Fracture; Hepatic Enzyme Increased; Infection; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Off Label Use; Osteoporosis; Pain; Rash; Synovitis	Rituximab	S	Unknown	Not Reported
	Naproxen	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Naproxen	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Prednisone	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Risedronate	C	Oral	Not Reported
	Folic Acid	C		Not Reported
	Naproxen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17787135	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593552		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Allopurinol			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported

Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Product Complaint; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Apo-Amitriptyline	S	Unknown		Not Reported
	Amitriptyline Hydrochloride;Perphenazine	S	Unknown		Not Reported
	Amitriptyline Hydrochloride;Perphenazine	S	Unknown		Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Apo-Diclo	S	Unknown	Tablet (Enteric Coated)	Not Reported
	Apo-Diclofenac	S	Topical		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Arthrotec	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Celebrex	S	Unknown		Not Reported
	Celebrex	S			Not Reported
	Celecoxib	S	Unknown		Not Reported
	Diclofenac	S	Unknown		Not Reported
	Diclofenac	S	Unknown		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Lyrica	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported

Methotrexate	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Parenteral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Misoprostol	S	Unknown	Not Reported
Naprosyn [Naproxen]	S	Unknown	Not Reported
Nifedipine	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pregabalin	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Diclofenac Potassium	S	Unknown	Not Reported
Etanercept	S	Unknown	Not Reported
Naproxen	S	Unknown	Not Reported
Winpred	S	Unknown	Not Reported
Tofacitinib	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17794311	EXPEDITED (15-DAY)		DE	IT-TEVA-2020-IT-1235086		77 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Erythema Multiforme; Neutrophilia; Off Label Use; Rash Erythematous	Darunavir			S	Oral	800 Mg		Teva
	Plaquenil			S	Oral	400 Mg		Not Reported
	Ritonavir Sandoz			S	Oral	100 Mg		Not Reported
	Soldesam			C	Intravenous (not otherwise specified)	1 Dosage Form		Not Reported

Bisoprolol Fumarate	C	Oral	1.25 Mg		Not Reported
Perindopril	C	Oral	5 Mg		Not Reported
Atorvastatin	C	Oral	40 Mg		Not Reported
Cardioaspirin	C		1 Dosage Form		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17795117	EXPEDITED (15-DAY)		HO, LT, OT	JP-ASCEND THERAPEUTICS US, LLC-2083841		41 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Disorder; Hormone Level Abnormal; Hormone Level Abnormal; Hypogonadism; Hypogonadism; Infarction; Maternal Exposure During Pregnancy; Pelvic Infection; Placenta Accreta; Pre-Eclampsia; Proteinuria; Vaginal Haemorrhage; Vaginal Haemorrhage	Estrogel			S				Ascend
	Progesterone (Progesterone) (Vaginal Tablet), Unknown			S	Vaginal			Not Reported
	Tacrolimus Monohydrate (Tacrolimus Monohydrate), Unknown			S				Not Reported
	Dydrogesterone (Dydrogesterone), Unknown			S	Oral			Not Reported
	Prednisolone			S				Not Reported
	Hydroxychloroquine (Hydroxychloroquine), Unknown			S				Not Reported
	Estradiol			S	Transdermal			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17805102	EXPEDITED (15-DAY)		OT	BR-ADVANZ PHARMA-202005005322			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Asthenia; Malaise; Pain; Rheumatoid Arthritis; Rheumatoid Factor Quantitative Increased; Therapy Cessation	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia
	Concor			C		Unk		Not Reported
	Libian21			C				Not Reported
	Rosuvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17812623	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1049359		77 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Off Label Use	Lopinavir/Ritonavir			S	Oral	1 Gram, Qd		Not Reported
	Plaquenil /00072602/			S	Oral	400 Milligram, Qd		Mylan
	Roactemra			S	Intravenous (not otherwise specified)	640 Milligram, Total		Mylan
	Ceftriaxone Disodium			C	Unknown	Unk		Mylan
	Urbason Solub			C	Unknown	40 Milligram		Mylan
	Dalacin C /00166001/			C	Unknown	Unk		Mylan
	Kayexalate			C	Oral	28 Gram		Mylan
	Magnesium Sulfate			C	Intravenous (not otherwise specified)	1 Gram		Mylan
	Lasix /00032601/			C	Intravenous (not otherwise specified)	40 Milligram		Mylan
	Heparin			C	Unknown	2500 Kilo-International Unit		Mylan
	Clindamicina Fosfato			C	Unknown	1800 Milligram		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17813083	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3408479-00		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome	Kaletra			S	Oral			Not Reported
	Hidroxicloroquina			S	Oral			Not Reported
	Hidroxicloroquina			S	Oral			Not Reported
	Interferon Beta 1b			S	Unknown			Not Reported
	Interferon Beta 1b			S	Unknown			Not Reported
	Azitromicina			S	Oral			Not Reported

Azitromicina	S	Oral	Not Reported
Paracetamol	C	Intravenous (not otherwise specified)	Not Reported
Enoxaparina	C	Subcutaneous	Not Reported
Insulina Novorapid	C	Subcutaneous	Not Reported
Acetilcisteina	C	Oral	Not Reported
Omeprazol	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17842961	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606547			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Methotrexate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848251	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP011212			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Alendronate			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Cetirizine			S	Unknown	Unk		Apotex
	Folic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848291	EXPEDITED (15-DAY)		OT	CO-ABBVIE-19K-036-3214198-00			Female	COL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Pain; Discomfort; Dizziness; Dry Eye; Dry Mouth; Eye	Humira 40mg/0.4ml			S	Subcutaneous			Not Reported
	Deflazacort			S	Unknown			Not Reported

Inflammation; Fibromyalgia; Gastritis; Hernia; Inflammation; Insomnia; Intervertebral Disc Protrusion; Mobility Decreased; Mobility Decreased; Nausea; Oropharyngeal Pain; Pain; Pelvic Floor Dysfunction; Spinal Pain; Tachycardia; Weight Increased	Hydroxychloroquine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848306	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020021830		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition Aggravated; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Apo-Prednisone			S	Oral	1 Dosage Form, Once Daily (Qd)		Not Reported
	Arava			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Gold			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Not Reported
	Prednisone			S	Oral	20 Milligram, Once Daily (Qd)		Not Reported
	Remicade			S	Intravenous (not	500 Milligram		Not Reported

				otherwise specified)		
	Rituxan		S	Intravenous (not otherwise specified)	1000 Milligram, 2x/Day (Bid)	Not Reported
	Rituxan		S		1 Gram, 2x/Day (Bid)	Not Reported
	Rituximab		S		1000 Milligram, 2x/Day (Bid)	Not Reported
	Simponi		S		50 Milligram	Not Reported
	Sulfasalazine		S		Unk	Not Reported
	Tofacitinib Citrate		S		5 Milligram, 2x/Day (Bid)	Not Reported
	Xeljanz		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848313	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020212639			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Pneumonia; Pulmonary Mass; Tinnitus	Methotrexate Sodium			S	Unknown			Pfizer
	Ibuprofen			S	Unknown			Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			C	Unknown	5 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848330	EXPEDITED (15-DAY)		HO, OT	TR-IPCA LABORATORIES LIMITED-IPC-2020-TR-001729			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Left Ventricular Dysfunction; Toxicity To Various Agents	Hydroxychloroquine		S	Unknown	400 Milligram, Qd	Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848351	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242648		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848377	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245897		75 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	500 Milligrams, Daily		Sun
	Plaquenil			S	Oral	600 Milligrams, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848404	EXPEDITED (15-DAY)		DE, OT	MX-ADVANZ PHARMA-202005005679			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Off Label Use	Hydroxychloroquine			S		200 Mg, Bid		Concordia
	Hydroxychloroquine			S				Concordia
	Methylprednisolone			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Clarithromycin			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848419	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201908-001809			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Foetal Death	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg/Day And 400 Mg/Day Alternately		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg/Day And 400 M/Day Alternately		Concordia
	Prograf			C		Unk		Not Reported
	Persantin			C		Unk		Not Reported
	Prednisolone			C		Unk		Not Reported
	Edirol			C		Unk		Not Reported
	Edirol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848423	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042737		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Nephrolithiasis; Somnolence; Visual Impairment	Orencia	S	Unknown	Unk	Bristol Myers Squibb
	Acetaminophen	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Apo-Acetaminophen	S	Unknown	325 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	50 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	40 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	50 Milligram, Qd	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	2000 Milligram	Not Reported
	Tylenol	S	Unknown	2000 Milligram	Not Reported
	Acetaminophen;Codeine Phosphate	C	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported
	Hydromorphone Hcl	C	Unknown	Unk	Not Reported
	Meloxicam	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848440	EXPEDITED (15-DAY)		DS	GB-IPCA LABORATORIES			Unknown	GBR

LIMITED-IPC-2020-GB-001714

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Hypotension	Hydroxychloroquine			S	Unknown	800 Milligram		Ipca
	Mirabegron			C	Unknown	Unk		Not Reported
	Amoxicillin			C	Unknown	Unk		Not Reported
	Digoxin			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Adcal-D3			C	Unknown	Unk		Not Reported
	Bisoprolol			C	Unknown	Unk		Not Reported
	Omeprazole			C	Unknown	Unk		Not Reported
	Dabigatran			C	Unknown	Unk		Not Reported
	Alendronic Acid			C	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848564	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042910			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	680 Milligram, Qwk		Not Reported
	Actemra			S	Unknown	360 Milligram, Qwk		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every 1 Week		Not Reported
	Enbrel			S	Unknown	50 Milligram, 1 Every 1 Week		Not Reported

Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Unknown	12 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Qwk	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Qmo	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown	100 Milligram, 2 Every 1 Day	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Alendronate Sodium	C	Unknown	70 Milligram, Qwk	Not Reported
	Ciclosporin	C	Unknown	150 Milligram, 1 Every 24 Day	Not Reported
	Prednisone	C	Unknown	10 Milligram, Qd	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848600	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606568			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain;	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported

Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Diclofenac	S	Unknown	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848607	EXPEDITED (15-DAY)		HO	ES-ROCHE-2609953		72 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolytic Anaemia; Hypofibrinogenaemia	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported

	Tocilizumab	S			Not Reported
	Dolquine	S	Other	400 Mg Dia	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848664	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606545		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blister; Confusional State; Contraindicated Product Administered; Contusion; Drug Ineffective; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Off Label Use; Peripheral Swelling; Pruritus; Pyrexia; Rash; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Weight Increased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Abatacept			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Act Oxycodone Cr			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Chlorhexidine			S	Unknown			Not Reported
	Chlorhexidine Gluconate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Oxycodone	S	Unknown	Not Reported
	Oxycodone Terephthalate	S	Unknown	Not Reported
	Oxycodone And Acetaminophen	S	Unknown	Not Reported
	Simponi	S	Periarticular	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfamethoxazole	S	Unknown	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Pantoprazole	C		Not Reported
	Pantoloc [Pantoprazole]	C		Not Reported
	Arava	C		Not Reported
	Cetrizine	C		Not Reported
	Hydroxychloroquine Sulfate	C		Not Reported
	Ibuprofen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848683	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA135289			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody	Triamcinolone Acetonide			S		Unk		Sanofi
	Triamcinolone Acetonide			S	Intra-articular	Unk		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg/M2, Qw		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg/M2, Qow		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5 Mg/Kg, Qd		Sanofi
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Naproxen			S		Unk		Not Reported
	Naproxen			S		Unk		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported

Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting; Wheelchair User	Hydroxychloroquine	S	Oral	500 Mg/Kg, Qd	Sanofi
	Immunoglobulins (Human)	S	Intravenous (not otherwise specified)	3 Mg/Kg, Qd	Not Reported
	Immunoglobulins (Human)	S	Intravenous (not otherwise specified)	70 G	Not Reported
	Prednisone	S	Oral	3 Mg, Qd	Not Reported
	Prednisone	S	Oral	5 Mg, Qd	Not Reported
	Prednisone	S	Oral	3 Mg, Bid	Not Reported
	Prednisone	S	Oral	5 Mg, Bid	Not Reported
	Prednisone	S	Oral	1.3 Mg, Qd	Not Reported
	Naproxen Sodium	S			Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qow	Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg, Qw	Not Reported
	Enbrel	S	Subcutaneous	25.0 Mg, Qow	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Infliximab	S	Unknown	5 Mg	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg, Qw	Not Reported
	Kineret	S	Subcutaneous	50 Mg, Qd	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Qm	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Qd	Not Reported
	Gamastan	S	Intravenous (not otherwise specified)	70 G	Not Reported
	Tetanus Immunoglobulin	S	Intravenous (not otherwise specified)	Unk Unk, Qw	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Qow	Not Reported
	Triamcinolone Hexacetonide	S	Intra-articular	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848793	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-015772			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; Exposure During Pregnancy; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Live Birth; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Diclofenac			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Prednison			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S				Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Salazopyrine	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848962	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606933		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Intentional Product Use Issue; Nausea; Nodule; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Risedronate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848987	EXPEDITED (15-DAY)		OT	ES-SA-2020SA138605			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Hydroxychloroquine			S				Sanofi

	Ivermectin	S	Oral	12 Mg, 1x	Sanofi
	Enoxaparin Sodium	S	Intravenous (not otherwise specified)	40 Mg, Qd	Sanofi
	Tocilizumab	S	Intravenous (not otherwise specified)	600 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17849009	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606523			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17849024	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-248623		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Level Increased; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Intentional Product Use Issue	Hydroxychloroquine			S	Unknown	Unk (10-11 Grams)		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17849105	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606333			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased; Off Label Use	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17849173	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605500		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Graft; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Foot Operation; Herpes Zoster; Joint Swelling; Limb Discomfort; Malaise; Nausea; Nodule; Off Label Use; Osteoarthritis; Rectal Haemorrhage; Thyroid Cancer	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17849272	EXPEDITED (15-DAY)		OT	CA-ROCHE-2612226		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Renal Failure	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17849379	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-015791			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Actemra			S	Unknown	Not Specified		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil(Hydroxychloroquine Sulfate)			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous bolus			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17849523	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202004004125			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Peripheral Swelling; Product Availability Issue; Unevaluable Event	Hydroxychloroquine			S		Decreased Dose		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17849592	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2020211375		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Multiple Organ Dysfunction Syndrome; Off Label Use	Cefepime Hcl			S		Unk		Pfizer
	Cefepime Hcl			S				Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer
	Doxycycline Hyclate			S				Pfizer
	Linezolid			S		Unk		Pfizer
	Linezolid			S				Pfizer
	Sulfamethoxazole/Trimethoprim			S		Unk (Ds)		Pfizer
	Sulfamethoxazole/Trimethoprim			S				Pfizer
	Tobramycin			S		Unk		Pfizer
	Tobramycin			S				Pfizer
	Vancomycin Hcl			S		Unk		Pfizer
	Vancomycin Hcl			S				Pfizer
	Hydroxychloroquine			S		400 Mg, 2x/Day(On Day 0)		Not Reported
	Hydroxychloroquine			S		200 Mg, Daily(For Days 1-4)		Not Reported
	Oseltamivir			S		Unk		Not Reported
	Oseltamivir			S				Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	400 Mg, Single (1 Dose)		Not Reported
	Lopinavir + Ritonavir			S		400 Mg, 2x/Day		Not Reported

	Lopinavir + Ritonavir	S			Not Reported
	Tacrolimus	C		6 Mg, 2x/Day(With Goal Trough Level Of 4-6 Ng/Ml)	Not Reported
	Tacrolimus	C		Unk(60% Dose Reduction)	Not Reported
	Mycophenolic Acid	C		360 Mg, 2x/Day	Not Reported
	Immunoglobulin [Immunoglobulin Human Normal]	C	Intravenous (not otherwise specified)	10 G, Single	Not Reported
	Norepinephrine	C		Unk	Not Reported
	Micafungin	C		100 Mg, Daily	Not Reported
	Heparin	C	Intravenous drip	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17849690	EXPEDITED (15-DAY)		HO, LT, OT	CA-APOTEX-2017AP007784		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Autoimmune Disorder; Cognitive Disorder; Cushing'S Syndrome; Headache; Infusion Related Reaction; Leukopenia; Muscular Weakness; Paralysis; Proteinuria; Psychotic Disorder; Therapeutic Response Decreased	Apo-Azathioprine			S	Unknown	100 Mg, Qd		Not Reported
	Apo-Azathioprine			S	Unknown	50 Mg, Qd		Not Reported
	Apo-Azathioprine			S	Unknown	20 Mg, Qd		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Prednisone			S	Unknown	50 Mg, Qd		Not Reported
	Prednisone			S	Unknown	20 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Cellcept /01275102/			S	Unknown			Not Reported
	Procytox			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Procytox			S	Unknown	500 Mg, Q.O.Wk.		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Q.O.Wk.		Not Reported
	Rituxan			S				Not Reported
	Diphenhydramine Hydrochloride			C	Oral	50 Mg, Unk		Not Reported

Acetaminophen	C	Oral	1000 Mg, Unk		Not Reported
Acetaminophen	C	Unknown	100 Mg, Qd		Not Reported
Methylprednisolone Sodium Succinate	C	Intravenous (not otherwise specified)	Unk, Bid		Not Reported
Methylprednisolone Sodium Succinate	C	Unknown	Unk, Bid		Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17849861	EXPEDITED (15-DAY)		DE, OT	ES-ABBVIE-20K-144-3426262-00		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Pneumonia; Hepatitis Cholestatic	Kaletra 200/50			S	Oral			Not Reported
	Azitromicina			S	Oral			Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)			Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported
	Interferon Beta-1a			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17849988	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2606400		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Apo-Ibuprofen			S	Oral			Not Reported
	Apremilast			S	Oral			Not Reported
	Apremilast			S				Not Reported
	Apremilast			S				Not Reported

Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Benadryl [Diphenhydramine Hydrochloride]	S	Unknown		Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Codeine	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Infliximab	S	Oral		Not Reported
	Infliximab	S			Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Motrin [Ibuprofen]	S	Oral		Not Reported
	Motrin [Ibuprofen]	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Otezla	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Endocervical		Not Reported

	Stelara	S	Subcutaneous	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Colchicine	C	Unknown	Not Reported
	Dexilant	C	Oral	Not Reported
	Febuxostat	C		Not Reported
	Folic Acid	C		Not Reported
	Gravol	C		Not Reported
	Mogadon	C	Oral	Not Reported
	Nitrazepam	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850007	EXPEDITED (15-DAY)		HO	ES-ACCORD-183641		81 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatic Encephalopathy; Off Label Use; Pancytopenia	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Amoxicillin/Clavulanic Acid			S	Intravenous (not otherwise specified)	1 Gr Every 12 Hours X 5 Days Followed By 1gr Every 8 Hours X 6 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850039	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-015789		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Actemra			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Folic Acid	S	Unknown	Not Reported
Fosamax	S	Oral	Not Reported
Fosamax	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Oral	Not Reported
Plaquenil	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850040	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-015790		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug	Diclofenac			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Topicort			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported

Intolerance; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Topicort	S	Subcutaneous	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Golimumab	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine	S	Unknown	Not Reported

	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C		Not Reported
	Salazopyrin	C		Not Reported
	Tofacitinib Citrate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850043	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-015774		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased;	Diclofenac Sodium			S	Unknown	Not Specified		Not Reported
	Hydrocortisone Acetate			S	Subcutaneous			Valeant
	Hydrocortisone			S	Oral			Valeant
	Topicort			S	Subcutaneous			Not Reported
	Topicort			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S			Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Oral		Not Reported
	Folic Acid	S	Unknown	Not Specified	Not Reported
	Fosamax	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Golimumab	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown	Not Specified	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Paracetamol	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not		Not Reported

			otherwise specified)	
	Sarilumab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Unknown	Not Reported
	Sulfasalazine	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Salazopyrin	C	Unknown	Not Reported
	Atasol	C	Unknown	Not Reported
	Tofacitinib Citrate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850045	EXPEDITED (15-DAY)		DS, OT	CA-BAUSCH-BL-2020-015778		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis;	Diclofenac			S	Unknown			Not Reported
	Topicort			S	Cutaneous			Not Reported
	Actemra			S	Subcutaneous	Not Specified		Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfathalidine	S	Oral	Not Reported
	Sulfathalidine	S	Oral	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Salazopyrin	C	Unknown	Not Reported
	Atasol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850050	EXPEDITED (15-DAY)		DS	CA-BAUSCH-BL-2020-015793		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Pregnancy; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Topicort	S	Cutaneous	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine	S	Oral	Not Reported

Sulfate]				
Prednisone		S	Oral	Not Reported
Pseudoephedrine Hydrochloride		S	Unknown	Not Reported
Remicade		S	Intravenous (not otherwise specified)	Not Reported
Rituximab		S	Intravenous (not otherwise specified)	Not Reported
Simponi		S	Subcutaneous	Not Reported
Sulfasalazine		S	Oral	Not Reported
Sulfasalazine		S	Oral	Not Reported
Sulfathalidine		S	Unknown	Not Reported
Tofacitinib Citrate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850051	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-015792			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Desoximetasone			S	Oral			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Subcutaneous	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil (Hydroxychloroquine Phosphate)	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850058	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-015796		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During	Desoximetasone			S	Oral			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Pregnancy; Off Label Use; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850061	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-015809		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Cataract; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Eye Disorder; Glaucoma; Hernia; Herpes	Desoximetasone			S	Unknown			Not Reported
	Glumetza			S	Unknown			Santarus
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe, Subcutaneous Solution		Not Reported

Zoster; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Off Label Use; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Subcutaneous Solution	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Lyrica	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown	Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Altace	C	Unknown		Not Reported
	Arava	C	Unknown		Not Reported
	Asa	C	Unknown		Not Reported
	Codeine	C	Unknown		Not Reported
	D-Alpha Tocopherol	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Prednisone	C	Oral		Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850062	EXPEDITED (15-DAY)		DS	CA-BAUSCH-BL-2020-015814		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Topicort	S	Cutaneous		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Actemra	S	Subcutaneous	Not Specified	Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Oral		Not Reported

Prednisone	S	Oral	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Tofacitinib Citrate	S	Unknown	Not Reported
Cortisone Acetate	S	Topical	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850071	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606989		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

	Risedronate Sodium	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850123	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020212816			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Osteoporosis	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Xeljanz			S	Unknown	5 Mg		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850127	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020212675		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Red Blood Cell Sedimentation Rate Abnormal; Synovitis; X-Ray Abnormal	Enbrel			S	Unknown	50 Mg		Unknown
	Methotrexate Sodium			S	Oral	17 Mg		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Daily		Pfizer
	Sulfasalazine			S	Unknown	1.5 G, 2x/Day		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported
	Penicillin G [Benzylpenicillin]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Calcium			C		Unk		Not Reported

Hydroxychloroquine	C	Unknown	300 Mg		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	300 Mg		Not Reported
Prednisone	C	Unknown	10 Mg, Daily		Not Reported
Tylenol [Paracetamol]	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850129	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020212802		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral; Condition Aggravated; Drug Ineffective; Drug Intolerance; Herpes Zoster; Hypertension; Inflammation; Joint Swelling; Musculoskeletal Disorder; Musculoskeletal Stiffness; Pain; Pancreatitis; Peripheral Swelling; Pneumonia; Psoriatic Arthropathy; Scar	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Xeljanz			S	Unknown	5 Mg, 2x/Day		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil S			S	Unknown	Unk		Not Reported
	Enbrel			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850130	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020212633		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate Sodium			S	Subcutaneous	20 Mg, 1 Every 1 Weeks		Pfizer
	Enbrel			S	Subcutaneous	50 Mg		Unknown
	Sulfasalazine			S	Unknown	20 Mg, 2 Every 1 Days		Pfizer
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Mg, 1 Every 24 Hours		Not Reported
	Humira			S	Subcutaneous	20 Mg, 1 Every 24 Hours		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, 2 Every 1 Days	Not Reported
	Orencia	S	Unknown		Not Reported
	Prednisone	S	Oral	50 Mg, 1 Every 24 Hours	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850170	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006658		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	2000 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 G, Q.O.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Bid		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Orencia			S	Subcutaneous	750 Mg, Q.Wk.		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	2000 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	50 Mg, Bid		Not Reported
	Methotrexate			S	Parenteral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	Unk		Not Reported

Methotrexate	S	Other	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	2000 Mg, Unk		Not Reported
Xeljanz	C	Oral	50 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850185	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606520		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger Deformity; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rocuronium Bromide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850264	EXPEDITED (15-DAY)		HO, OT	CA-BAUSCH-BL-2020-015756		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Tinea; Bone Density Decreased; Cataract; Cellulitis; Contusion; Drug Ineffective; Fatigue;	Diltiazem			S	Unknown			Not Reported
	Magnesium		Y	S	Unknown			Not Reported
	Magnesium		Y	S				Not Reported

Glucose Tolerance Impaired; Herpes Zoster; Hyperlipidaemia; Hypertension; Impaired Quality Of Life; Impaired Work Ability; Infection Susceptibility Increased; Inhibitory Drug Interaction; Insomnia; Oral Herpes; Poor Quality Sleep; Purpura; Skin Disorder; Weight Increased	Pentoxifylline	S	Unknown	Unspecified Dosage Form	Not Reported
	Capsaicin	S	Topical		Not Reported
	Lithium Carbonate	S	Unknown	Unspecified Dosage Form	Not Reported
	Amitriptyline	S	Unknown		Not Reported
	Amlodipine Besilate	S	Unknown		Not Reported
	Anakinra	S	Unknown		Not Reported
	Apremilast	S	Unknown		Not Reported
	Bumetanid [Bumetanide]	S	Unknown		Not Reported
	Cimetidine	S	Unknown	Unspecified Dosage Form	Not Reported
	Clonidine	S	Unknown	Unspecified Dosage Form	Not Reported
	Etanercept	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Ibudilast	S	Unknown		Not Reported
	Ketamine	S	Topical		Not Reported
	Ketamine	S	Oral		Not Reported
	Ketamine	S	Intravenous (not otherwise specified)		Not Reported
	Lidocaine	S	Intravenous (not otherwise specified)		Not Reported
	Lidocaine	S	Topical		Not Reported
	Memantine	S	Unknown		Not Reported
	Metprolol	S	Unknown		Not Reported
	Mexiletine	S	Unknown		Not Reported
	Montelukast	S	Unknown	Unspecified Dosage Form	Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	N-Acetylcysteine	S	Unknown		Not Reported
	Naltrexone Hydrochloride	S	Unknown		Not Reported
	Palmitoylethanolamide	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported

Prednisone		S	Unknown	Not Reported
Prednisone		S	Unknown	Not Reported
Prednisone		S	Unknown	Not Reported
Pregabalin		S	Unknown	Not Reported
Spironolactone		S	Unknown	Not Reported
Vitamin B 2		S	Unknown	Not Reported
Vitamin B 2		S		Not Reported
Vitamin C		S	Unknown	Not Reported
Calcitonin		C	Unknown	Not Reported
Ezetimib		C	Unknown	Not Reported
Trazodone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850265	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606469			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain In Extremity; Peripheral Swelling;	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Therapeutic Product Effect Decreased; Upper Respiratory Tract Infection; White Blood Cell Count Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850357	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020214596			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Actinic Keratosis; Arthrodesis; Asthma; Coordination Abnormal; Dry Eye; Gastrointestinal Disorder; Nausea; Palpitations; Photosensitivity Reaction; Rash; Treatment Failure	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Unknown	1000 Mg, 2x/Day		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, 2x/Day		Pfizer
	Cimzia			S	Unknown	200 Mg, 1 Every 2 Weeks		Not Reported
	Cimzia			S	Unknown	200 Mg, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported
	Leflunomide			S	Unknown	10 Mg, 1x/Day		Not Reported
	Arava			C	Unknown			Not Reported
	Depo-Medrol			C	Unknown			Not Reported
	Pantoprazole			C	Unknown	40 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850417	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020212807			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Interstitial Lung Disease	Methotrexate Sodium	S	Unk		Pfizer
	Xeljanz	S	Unk		Pfizer
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Arava	S		20 Mg, 1x/Day	Not Reported
	Hydroxychloroquine	S		200 Mg, 1x/Day	Not Reported
	Orencia	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850433	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1241768		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva
	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported
	Enoxaparina (2482a)			S	Subcutaneous	60 Mg		Not Reported
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850438	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242746		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Treatment Failure	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Lyrica	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850525	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242831			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported

	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850535	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242908		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850537	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020212789		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Herpes	Enbrel			S	Unknown	Unk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer

Zoster; Hypertension; Pneumonia	Xeljanz		S	Oral	5 Mg, 1 Every 12 Hours	Pfizer
	Arava		S	Unknown	Unk	Not Reported
	Humira		S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850545	EXPEDITED (15-DAY)		HO, LT	IT-ACCORD-183867		88 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gamma-Glutamyltransferase Increased; Hypertransaminasaemia; Off Label Use	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850620	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3426267-00		57 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hyperbilirubinaemia	Kaletra 200/50			S	Oral			Not Reported
	Dolquine			S	Oral			Not Reported
	Azitromicina			S	Intravenous (not otherwise specified)			Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850703	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606929			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

Use; Pemphigus; Systemic Lupus Erythematosus			otherwise specified)	
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Prednisone	S		Not Reported
	Arava	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850889	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606964			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Cimzia	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850911	EXPEDITED (15-DAY)		DE	MX-ADVANZ PHARMA-202005005727			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Respiratory Disorder	Hydroxychloroquine			S		200 Mg, Bid		Concordia
	Hydroxychloroquine			S				Concordia
	Clarithromycin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850937	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242799		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cough; Drug Intolerance; Dyspnoea; Forced Vital Capacity Decreased; Lung Diffusion Test Decreased; Pulmonary Function Test Decreased; Therapy Non-Responder; Treatment Failure	Mycophenolate Mofetil			S	Oral			Teva
	Mycophenolate Mofetil			S	Unknown	1440 Milligram Daily;		Not Reported
	Cyclophosphamide			S	Unknown	150 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Domperidone			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851322	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242756		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851324	EXPEDITED (15-DAY)		OT	NVSC2020US151019			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine Sulfate Tablets Usp			S	Transplacental	Maternal Dose: Unk		Novartis
	Betamethasone			S	Transplacental	Maternal Dose: Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851342	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242665		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cough; Drug Intolerance; Dyspnoea; Forced Vital Capacity Decreased; Lung Diffusion Test Decreased; Pulmonary Function Test Decreased; Therapy Non-Responder; Treatment Failure	Mycophenolate Mofetil			S	Oral			Teva
	Mycophenolate Mofetil			S				Teva
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Mycophenolate Sodium			S	Unknown	1440 Milligram Daily;		Not Reported
	Procytox			S	Intravenous (not otherwise specified)	150 Milligram Daily;		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Cymbalta			C	Unknown			Not Reported
	Domperidone			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851365	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242757		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851480	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242848			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851483	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-			Female	CAN

1242904

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Piroxicam			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851519	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242888			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr

Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851520	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242758		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851523	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242818			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Piroxicam			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851555	EXPEDITED (15-DAY)		HO, LT	US-TEVA-2020-US-1242208		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Intentional Overdose; Tachycardia	Hydroxychloroquine		S	Oral	Approximately 10-11 Gram	Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851573	EXPEDITED (15-DAY)		OT	NVSC2020US151024			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine Sulfate Tablets Usp			S	Transplacental	Maternal Dose: Unk		Novartis
	Betamethasone			S	Transplacental	Maternal Dose: Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851592	EXPEDITED (15-DAY)		OT	NVSC2020US151023			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine Sulfate Tablets Usp			S	Transplacental	Maternal Dose: Unk		Novartis
	Betamethasone			S	Transplacental	Maternal Dose: Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851593	EXPEDITED (15-DAY)		DE	CA-ROCHE-2610888		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported

Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sepsis; Synovitis; Terminal State; Thrombosis	Actemra	S	Unknown	Not Reported
	Doxycycline Hyclate	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851594	EXPEDITED (15-DAY)		OT	CA-ROCHE-2610044			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported

Simponi	C		Not Reported
Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851614	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606970		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Actonel			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851659	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020206955		42 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	250 Mg, 1x/Day		Pfizer
	Hydroxyzine Hydrochloride			S	Intravenous (not otherwise specified)	25 Mg Every 6 Hours		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, Every 12 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851672	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020212770			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Musculoskeletal Pain; Nausea; Neck Pain; Pain In Extremity; Rash; Therapeutic Product Effect Decreased; Treatment Failure; Weight Decreased	Codeine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Endocervical	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851705	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-015787			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Discomfort; Drug Ineffective; Drug	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Wound	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Oral	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Topicort	S	Subcutaneous	Not Reported
	Xeljanz	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851707	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606940		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851753	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609779			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Tocilizumab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851764	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3426540-00		59 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Long Qt Syndrome	Kaletra 200/50			S	Oral			Not Reported
	Dolquine			S	Oral			Not Reported
	Azitromicina			S	Oral			Not Reported
	Ceftriaxona			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851794	EXPEDITED (15-DAY)		HO	CA-ROCHE-2606340			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Unknown	Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851809	NON-EXPEDITED			US-AMNEAL PHARMACEUTICALS-2020-AMRX-01271			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Hydroxychloroquine Sulfate			S	Unknown	Unk		Amneal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851835	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609717		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis	Rituximab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851836	EXPEDITED (15-DAY)		HO	CA-ROCHE-2605493		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Ineffective; Fall; Fatigue; Femur Fracture; Haematocrit Decreased;	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Atenolol			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Co Atenolol			S	Unknown			Not Reported

Haemoglobin Decreased; Impaired Healing; Joint Swelling; Multiple Fractures; Musculoskeletal Pain; Osteoporosis; Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Enbrel	S	Subcutaneous	Not Reported
	Etanercept	S	Unknown	Not Reported
	Ferrous Fumarate	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Naprosyn [Naproxen]	S	Unknown	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Palafer	S	Unknown	Not Reported
	Palafer Cf	S	Unknown	Not Reported
	Pantoprazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851958	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606524		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported

Systemic Lupus Erythematosus	Desoximetasone		S	Oral	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Folic Acid		S	Unknown	Not Reported
	Fosamax		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Orencia		S	Subcutaneous	Not Reported
	Phthalylsulfathiazole		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17852095	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043010		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Drug Intolerance; Synovitis; Throat Tightness	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Milligram (2 In Every 1		Not Reported

							Day)			
	Supeudol			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17852176	EXPEDITED (15-DAY)		DE, HO	ES-ROCHE-2612707		70 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Bundle Branch Block Right; Hypertension; Hypofibrinogenaemia; Pneumonia Escherichia; Ventricular Tachycardia	Hydroxychloroquine			S	Oral	400 Mg Dia		Not Reported
	Hydroxychloroquine			S				Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab			S				Not Reported
	Azitromicina			S	Intravenous (not otherwise specified)	500 Mg Dia		Not Reported
	Azitromicina			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17852203	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3426275-00		63 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic; Long Qt Syndrome	Kaletra 200/50			S	Oral			Not Reported
	Dolquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17853043	EXPEDITED (15-DAY)		HO	ES-ROCHE-2609940		54 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Haemolytic Anaemia; Hepatitis; Hyperbilirubinaemia; Rectal Haemorrhage	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Dolquine			S	Oral	400 Mg Dia		Not Reported
	Paracetamol			S	Intravenous (not otherwise specified)	1gr Cada 8 Horas		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17853056	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606909			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Musculoskeletal Stiffness; Pain; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17853719	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3426767-00		33 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia; Liver Disorder	Kaletra 200/50			S	Oral			Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)			Not Reported
	Azitromicina			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17853720	EXPEDITED (15-DAY)		HO	LU-ABBVIE-20K-098-3426807-00		74 YR	Female	LUX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Kaletra			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

Plaquenil	S	Oral		Not Reported
Nimbex	S	Intravenous (not otherwise specified)	10mg/5ml	Not Reported
Ceftriaxone Kabi	S	Intravenous (not otherwise specified)		Not Reported
Propofol	C	Intravenous (not otherwise specified)		Not Reported
Paracetamol	C	Intravenous (not otherwise specified)		Not Reported
Paracetamol	C			Not Reported
Clexane	C	Subcutaneous		Not Reported
Simvastatine	C	Oral	Long Term Treatment, Continued	Not Reported
Nexiam	C	Intravenous (not otherwise specified)		Not Reported
Sufenta	C	Intravenous (not otherwise specified)	50 Microgrammes/10 Ml	Not Reported
Lysomucil	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17853744	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3427722-00		84 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperbilirubinaemia; Hypertransaminasaemia	Kaletra 200/50			S	Oral			Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17853748	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3426655-00		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Kaletra 200/50			S	Oral			Not Reported

	Ceftriaxona		S	Intravenous (not otherwise specified)	Not Reported
	Hidroxicloroquina Sulfato		S	Oral	Not Reported
	Azitromicina		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17853749	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3427730-00		33 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gamma-Glutamyltransferase Increased; Hypertriglyceridaemia	Kaletra 200/50			S	Oral			Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17853757	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042754			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	200 Milligram		Not Reported
	Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Arava			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported

	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17853763	EXPEDITED (15-DAY)		DS	CA-ROCHE-2606293		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Disorder; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy;	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronate Sodium			S				Not Reported
	Alendronic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Ibuprofen			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apremilast			S	Unknown			Not Reported
	Apremilast			S	Unknown			Not Reported
	Apremilast			S				Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Cyclosporin A			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Tongue Disorder; Ulcer	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Ibuprofen	S	Oral	Not Reported
	Infliximab	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Motrin [Ibuprofen]	S	Oral	Not Reported
	Myochrysine	S	Intramuscular	Not Reported

Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Otezla	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Stelara	S	Subcutaneous	Not Reported
Sulfasalazine	S	Endocervical	Not Reported
Tocilizumab	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Rituxan	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17853895	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042761			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetrizine			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported

Enbrel	S	Unknown	Unk		Not Reported
Folic Acid	S	Unknown	Unk		Not Reported
Fosamax	S	Other	Unk		Not Reported
Humira	S	Subcutaneous	40 Milligram		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	12308608	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-1745459		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 365.0 Nos		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Oral		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral	11.0 Years	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported

Orencia	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Desoximetasone	S	Oral	Not Reported
Desoximetasone	S	Cutaneous	Not Reported
Desoximetasone	S	Oral	Not Reported

Desoximetasone	S	Unknown		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Cortisone	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Sulfathalidine	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Cetirizine Hydrochloride	S	Unknown		Not Reported
Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Cortisone Acetate	S	Unknown		Not Reported
Diclofenac Sodium	S	Unknown		Not Reported
Paracetamol	S	Unknown		Not Reported
Sarilumab	S	Unknown		Not Reported
Stelara	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Duration- 365	Not Reported
Alendronate Sodium	S	Oral		Not Reported
Alendronate Sodium	S	Unknown		Not Reported
Alendronate Sodium	S	Oral		Not Reported
Cortisone	S	Oral		Not Reported
Cortisone	S	Oral		Not Reported
Cortisone	S	Oral		Not Reported
Acetaminophen	S	Unknown		Not Reported
Apo Hydroxyquine	S	Unknown		Not Reported
Apo Hydroxyquine	S	Unknown		Not Reported
Apo-Folic Acid	S	Unknown		Not Reported
Hydroxychloroquine Phosphate	S	Oral		Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Adalimumab	S	Subcutaneous		Not Reported

Etanercept	S	Subcutaneous		Not Reported
Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C			Not Reported
Zyrtec-D	C			Not Reported
Salazopyrin	C			Not Reported
Ibuprofen	C	Unknown		Not Reported
Leflunomide	C	Oral		Not Reported
Lisinopril	C	Unknown		Not Reported
Prednisolone	C	Unknown		Not Reported
Vitamin D3	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	12774372	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076813		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Condition Aggravated; Drug Ineffective; Frustration Tolerance Decreased; Ill-Defined Disorder; Impaired Work Ability; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis; Suicidal Ideation; Swelling; Treatment Failure; Vein Disorder	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	162 Milligram		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Enbrel			S	Unknown	50.0 Milligram		Not Reported
	Gold			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

Hydroxychloroquine	S	Unknown	Unk		Not Reported
Apo-Prednisone	S	Unknown	5.0 Milligram		Not Reported
Fosamax	C	Unknown	Unk		Not Reported
Ibuprofen	C	Unknown	Unk		Not Reported
Lisinopril	C	Unknown	Unk		Not Reported
Vitamin D3	C	Unknown	Unk		Not Reported
Alendronate Sodium	C	Unknown	Unk		Not Reported
Fosavance	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	12913342	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092065		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Orencia			S	Unknown	Unk, Qmo		Bristol Myers Squibb
	Cimzia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50.0 Milligram, Qwk		Not Reported
	Actemra			S	Unknown	50 Milligram, Qwk		Not Reported
	Actemra			S	Unknown	4.0 Milligram/Kilogram		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	1 Gram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

Hydroxychloroquine	S	Unknown	200 Milligram, Qd		Not Reported
Hydroxychloroquine	S	Oral	300 Milligram, Qd		Not Reported
Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
Rituximab	S	Unknown	1 Gram		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Adalimumab	S	Unknown	Unk		Not Reported
Leflunomide	C	Unknown	20 Milligram, Qd		Not Reported
Methotrexate	C	Oral	Unk		Not Reported
Methotrexate	C	Subcutaneous	20 Milligram		Not Reported
Methotrexate	C	Unknown	0.8 Milliliter, Qwk		Not Reported
Xeljanz	C	Oral	5 Gram, Bid		Not Reported
Tocilizumab	C	Endocervical	Unk		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported
Celebrex	C	Unknown	Unk		Not Reported
Diclofenac	C	Unknown	Unk		Not Reported
Lyrica	C	Unknown	Unk		Not Reported
Valsartan	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	12914292	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092847		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Arthropathy; Back Disorder; Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Q4wk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Qmo		Bristol Myers Squibb
	Orencia			S	Intravenous (not	500 Milligram		Bristol Myers Squibb

Intolerance; Knee Arthroplasty; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash			otherwise specified)		
	Orencia	S	Intravenous (not otherwise specified)	500 Milligram, Q4mo	Bristol Myers Squibb
	Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Anakinra	S	Subcutaneous	100 Milligram, Qd	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira	S	Subcutaneous	Unk Unk, Qwk	Not Reported
	Humira	S	Unknown	40 Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	12.5 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	12.5 Milligram, Q2wk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Q2wk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	12.5 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	20 Milligram, Cyclical	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Leflunomide	S	Unknown	Unk,Qd	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Qwk	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Q2wk	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, 1 Every 1 Day	Not Reported
	Xeljanz	C	Oral	5 Milligram, Two Time In A Week	Not Reported

	Xeljanz	C	Unknown	Unk Unk, Bid	Not Reported
	Xeljanz	C	Unknown	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	12928888	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091881			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Limb Discomfort; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8.0 Millilitre Per Kilogram		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Anakinra			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Qh		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Qcycle		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qh		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	35 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

Rituxan	S	Intravenous (not otherwise specified)	1 Gram, Qcycle	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Actonel	S	Oral	35 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	300 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk, Qwk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qh	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qcycle	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	1 Dosage Form, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Risedronate Sodium	S	Unknown	35 Milligram, One Every One Week	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Xeljanz	S	Oral	10 Milligram, Qd	Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Risedronic Acid	S	Unknown	35 Milligram, Qwk	Not Reported
Hydroxychloroquine	C	Unknown	300 Milligram, Qd	Not Reported
Risedronate	C	Unknown		Not Reported
Methotrexate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	13169280	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		78 YR	Female	CAN

BMS-2017-005325

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	20 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Milligram, 4 Every 1 Week		Not Reported
	Hydroxychloroquine Phosphate			S	Oral	200 Mg, Bid		Not Reported
	Prednisone			S	Oral	5 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200.0 Milligram, 2 Every 1 Day		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Apo-Prednisone			S	Oral	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	13229205	EXPEDITED (15-DAY)		DS	CA-ROCHE-1892598		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Disease Recurrence; Drug Ineffective; Dyspnoea; Impaired Work Ability; Infection; Insomnia; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Off Label Use; Pain; Peripheral Swelling; Physical Disability; Rash; Rheumatoid Arthritis; Skin Mass; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapeutic Product Effect Decreased; Therapy Non-Responder	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Cyclical	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Apo-Hydroxyquine	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Prednisone Acetate	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Tofacitinib Citrate	S	Oral		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Risedronate Sodium	C	Unknown		Not Reported
	Sulfasalazine	C	Oral		Not Reported
	Sulfasalazine	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	13362332	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP008455			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Prednisone			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Ramipril			S	Oral	Unk, Qd		Apotex
	Dorzolamide ,Timolol			S	Unknown	Unk Unk, Bid		Apotex
	Dorzolamide ,Timolol			S	Unknown	1 Df, Bid		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Levothyroxine			S	Unknown	Unk, Qd		Not Reported
	Levothyroxine			S	Unknown	1 Df, Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk, Qd		Not Reported
	Tylenol /00020001/			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	14917261	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-069816		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Blood Creatinine Increased; Diarrhoea; Drug Ineffective; Limb Discomfort; Musculoskeletal Discomfort; Pain; Pharyngeal Oedema; Rheumatoid Arthritis;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

Therapeutic Product Effect Decreased	Sulfasalazine	S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Penicillin G [Benzylpenicillin]	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	C	Unknown			Not Reported
	Methotrexate	C	Unknown			Not Reported
	Arava	C	Unknown			Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	14921384	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043876		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Back Pain; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	20 Milligram, Qd		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	200 Milligram, Bid		Not Reported
	Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram, Bid		Not Reported
	Leflunomide			S	Unknown	10 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	14921794	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044644			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous	162 Mg, 2 Every One Week		Not Reported
	Actemra			S	Subcutaneous	162 Milligram, Q2wk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	400 Mg, 3 Times/Wk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	200 Mg, 2 Times/Wk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	200 Milligram, Q2wk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, 2 Times/Wk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	20 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	14979598	EXPEDITED (15-DAY)		OT	CA-ROCHE-2135227			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	152.0 Days		Not Reported

Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Acetaminophen	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Acetaminophen;Codeine Phosphate	C	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported

	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Synthroid	C	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported
	Hydromorphone Hcl	C	Unknown	Not Reported
	Tylenol With Codeine No.3	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	15100606	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0751		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tocilizumab			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported

	Prednisone	C			Not Reported
	Desoximetasone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	15311145	EXPEDITED (15-DAY)		DS, HO, OT	CA-APOTEX-2016AP014163		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Fall; Fatigue; Femur Fracture; Haematocrit Decreased; Haemoglobin Decreased; Impaired Healing; Joint Swelling; Multiple Fractures; Musculoskeletal Pain; Off Label Use; Osteoporosis; Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Naproxen			S	Oral	100 Mg, Qd		Apotex
	Naproxen			S	Oral	500 Mg, Bid		Apotex
	Naproxen			S	Oral	1000 Mg, Qd		Apotex
	Folic Acid			S	Unknown	5 Mg Twice In A Week		Not Reported
	Folic Acid			S	Unknown	400 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Bid		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Q.O.Wk.		Not Reported
	Folic Acid			S	Unknown	400 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	40 Mg, Unknown		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	40 Mg, Qd		Apotex
	Pantoprazole			S	Unknown	40 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Atenolol			S	Unknown	25 Mg, Qd		Apotex
	Celecoxib			S	Unknown	Unk		Apotex
	Sulfasalazin			S	Oral	500 Mg, Bid		Not Reported
	Sulfasalazin			S	Oral	1000 Mg, Bid		Not Reported
	Co Atenolol			S	Unknown	25 Mg, Qd		Not Reported
	Co Atenolol			S	Unknown	20 Mg, Qd		Not Reported

Methotrexate Sodium	S	Oral	20 Mg, Q.Wk.	Not Reported
Methotrexate Sodium	S	Oral	25 Mg, Q.Wk.	Not Reported
Methotrexate Sodium	S	Oral	25 Mg, 1 Every 2 Weeks	Not Reported
Methotrexate Sodium	S	Oral	20 Mg, Q.O.Wk.	Not Reported
Palafer Cf	S	Unknown	Unk Unk, Qd	Not Reported
Pantoloc /01263204/	S	Unknown	40 Mg, Qd	Not Reported
Pantoloc /01263204/	S			Not Reported
Arava	S	Unknown	20 Mg, Qd	Not Reported
Arava	S	Oral	20 Mg, Qd	Not Reported
Naprosyn /00256201/	S	Oral	500 Mg, Bid	Not Reported
Naprosyn /00256201/	S	Oral	1000 Mg, Qd	Not Reported
Naprosyn /00256201/	S	Oral	100 Mg, Qd	Not Reported
Plaquenil /00072602/	S	Unknown	200 Mg, Bid	Not Reported
Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
Plaquenil /00072602/	S	Unknown	40 Mg, Qd	Not Reported
Enbrel	S	Subcutaneous	Unk, Unknown	Not Reported
Humira	S	Subcutaneous	Unk, Unknown	Not Reported
Orencia	S	Unknown	Unk,	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk, Unknown	Not Reported
Abatacept	S	Unknown	Unk, Unknown	Not Reported
Ascorbic Acid	S	Unknown	Unk, Unknown	Not Reported
Ascorbic Acid	S	Unknown	Unk, Qd	Not Reported
Ferrous Fumarate	S	Unknown	Unk, Unknown	Not Reported
Ferrous Fumarate W/Folic Acid	S	Unknown	Unk, Qd	Not Reported
Pantoprazole Sodium Sesquihydrate	S	Unknown	40 Mg, Qd	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	25 Mg, Qd	Not Reported

Methotrexate	S	Oral	25 Mg, Q.Wk.		Not Reported
Methotrexate	S	Oral	25 Mg, Unk		Not Reported
Methotrexate	S	Oral	Unk Unk, Q.O.Wk.		Not Reported
Methotrexate	S	Oral	20 Mg, Qd		Not Reported
Methotrexate	S	Oral	20 Mg, Q.Wk.		Not Reported
Methotrexate	S	Oral	20 Mg, Q.O.Wk.		Not Reported
Etanercept	S	Subcutaneous	Unk		Not Reported
Palafer	S	Unknown	Unk		Not Reported
Teva Pantoprazole	S	Unknown	40 Mg, Qd		Not Reported
Vitamin C /00008001/	S	Unknown	Unk, Qd		Not Reported
Actemra	S	Unknown	Unk		Not Reported
Xeljanz	S	Unknown	Unk		Not Reported
Celebrex	C	Oral	200 Mg, Qd		Not Reported
Celebrex	C	Unknown	Unk		Not Reported
Prednisone	C	Intracardiac	5 Mg, Qd		Not Reported
Prednisone	C	Unknown	Unk Unk, Q.O.Wk.		Not Reported
Celecoxib	C	Oral	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	15350864	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013388		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Operation; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Acetaminophen			S	Unknown	Unk		Apotex
	Apo-Prednisone			S	Unknown	5 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported

	Methotrexate	S	Subcutaneous	25 Mg, Unk		Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Four Every One Week		Not Reported
	Plaquenil /00072602/	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	15402622	EXPEDITED (15-DAY)		HO, OT	CO-ACTELION-A-CH2018-179017		63 YR	Female	COL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Acute Oesophageal Mucosal Lesion; Angina Unstable; Anxiety; Arrhythmia; Asthenopia; Blood Creatinine Increased; Bronchitis; Cardiac Failure; Chest Discomfort; Chest Pain; Choking; Chronic Kidney Disease; Coagulation Time Prolonged; Coagulopathy; Constipation; Diarrhoea; Discomfort; Dizziness; Dyspnoea; Ear Disorder; Eye Disorder; Fall; Fatigue; Feeling Abnormal; Fibromyalgia; Flatulence; Fluid Retention; Gait Disturbance; General Physical Health Deterioration; Haematemesis; Head Discomfort; Headache; Heart Disease Congenital; Hyponatraemia; Hypotension;	Tracleer			S	Oral	62.5 Mg, Bid		Actelion
	Opsumit			S	Oral	10 Mg, Qd		Actelion
	Opsumit			S	Oral	10 Mg, Od		Actelion
	Opsumit			S	Oral	10 Mg, Od		Actelion
	Opsumit			S	Oral	10 Mg, Qd		Actelion
	Opsumit			S	Oral	10 Mg, Qd		Actelion
	Opsumit			S	Oral	10 Mg, Qd		Actelion
	Riociguat			S	Unknown	Unk		Not Reported
	Hidroxicloroquina			S	Unknown			Not Reported
	Levetiracetam			S	Unknown			Not Reported
	Carvedilol			C				Not Reported

Hysterectomy; Inflammation; Inflammation Of Wound; Intestinal Obstruction; Joint Swelling; Loss Of Control Of Legs; Malaise; Memory Impairment; Mitral Valve Calcification; Mitral Valve Disease; Musculoskeletal Pain; Nervous System Disorder; Pain In Extremity; Peripheral Swelling; Product Availability Issue; Pulmonary Artery Occlusion; Reflux Gastritis; Renal Disorder; Swelling; Swelling Face; Swelling Of Eyelid; Syncope; Tremor; Vasodilatation; Walking Aid User; Walking Disability; Wheelchair User

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	15457719	EXPEDITED (15-DAY)		OT	CA-ROCHE-2191504		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Off Label Use; Product Use Issue; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	15632273	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105425		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	500 Milligram		Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	25 Mg, Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)		
	Simponi	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	400 Milligram, Qd	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	15639542	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-106082		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anti-Neutrophil Cytoplasmic Antibody Positive Vasculitis; Arthralgia; Chest Pain; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Hypersensitivity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Nausea; Pain; Proteinuria; Rheumatoid Arthritis; Treatment Failure; Vasculitis	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	162 Milligram, Q2wk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Gold			S	Intramuscular	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Penicillamine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	50 Mg, Qmo		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported

Azathioprine	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Etanercept	S	Subcutaneous	25 Milligram, 2 Times/Wk	Not Reported
Imuran [Azathioprine Sodium]	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
Leflunomide	S	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported
Azathioprine	C	Oral	200 Milligram, Qd	Not Reported
Cyclophosphamide	C	Intravenous (not otherwise specified)		Not Reported
Docusate Sodium	C	Oral	100 Milligram, Qd	Not Reported
Doxycycline	C	Oral	Unk, 2 Every Day	Not Reported
Elavil [Allopurinol]	C	Unknown	Unk	Not Reported
Prednisone	C	Oral	8 Mg, Qd	Not Reported
Sulfasalazine	C	Unknown	Unk	Not Reported
Sulfasalazine	C	Oral	1.5 Gram, Bid	Not Reported
Tobramycin	C	Unknown	0.3 Percent, Qid	Not Reported
Wellbutrin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	15809559	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2616794-00		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Animal Bite; Drug Ineffective; Emotional Disorder; Herpes Zoster; Inappropriate Schedule Of Product Administration; Malignant Melanoma;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

Mobility Decreased; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Victim Of Crime	Methotrexate		S	Oral	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Prednisone		C	Oral	Not Reported
	Restasis		C		Not Reported
	Sulfasalazine		C	Oral	Not Reported
	Synthroid		C		Not Reported
	Folic Acid		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	16388804	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-050997		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Treatment Failure; Visual Impairment	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown	20.0 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400.0 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Methotrexate			C	Subcutaneous	15.0 Milligram, Qwk		Not Reported
	Methotrexate			C	Subcutaneous	17.5 Milligram, Qwk		Not Reported

	Sulfasalazine	C	Oral	1.0 Gram, Qd	Not Reported
	Xeljanz	C	Oral	5.0 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17024990	EXPEDITED (15-DAY)		OT	CA-ROCHE-2459482		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Off Label Use; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported
	Remicade			C	Intravenous (not otherwise specified)			Not Reported
	Synthroid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17154604	EXPEDITED (15-DAY)		OT	CA-ROCHE-2457097			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Solution For Injection		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solutiom		Not Reported

	Sulfasalazine		S	Oral	Not Reported
	Tofacitinib Citrate		S	Unknown	Not Reported
	Adalimumab		S	Subcutaneous	Not Reported
	Cetirizine Hydrochloride		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17206018	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6073			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Diabetes Mellitus; Drug Ineffective; Flank Pain; Leukaemia; Lymphoma; Neutrophil Count Increased; Splenomegaly; White Blood Cell Count Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cortisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17209201	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-121339			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

	Fosamax	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17259832	EXPEDITED (15-DAY)		OT	CA-ROCHE-2513906		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

	Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lyrica	C	Oral	Not Reported
	Naproxen	C	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17359891	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532661			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Kineret			S	Subcutaneous	100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown			Not Reported

Vomiting; Wheelchair User	Adalimumab	S	Subcutaneous	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Gamastan	S	Intramuscular	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Immunoglobulins (Human)	S	Intravenous (not otherwise specified)	Not Reported
	Immunoglobulins (Human)	S	Intravenous (not otherwise specified)	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Tetanus Immunoglobulin	S	Intravenous (not otherwise specified)	Not Reported
	Triamcinolone Acetonide	S	Unknown	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Not Reported
	Triamcinolone Acetonide	S		Not Reported
	Triamcinolone Hexacetonide	S	Intra-articular	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17412591	EXPEDITED (15-DAY)		HO	CA-ROCHE-1866268		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Allergic Oedema; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Infection; Rash; Rheumatoid Arthritis; Urticaria	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported

	Arava	S	Unknown	Not Reported
	Cefazolin	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Viread	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17660317	NON-EXPEDITED			US-PFIZER INC-2020147388		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use; Product Use In Unapproved Indication; Therapeutic Response Unexpected	Azithromycin			S		Unk		Pfizer
	Hydroxychloroquine Sulfate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17681180	EXPEDITED (15-DAY)		DS, HO, LT, OT	NVSC2020SK101566			Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction; No Adverse Event; Oligohydramnios; Premature Baby	Metoprolol Tartrate			S	Transplacental	Unk		Novartis
	Etamsylate			S	Transplacental	Unk		Not Reported
	Dexamethasone			S	Transplacental	Unk		Not Reported
	Dexamethasone			S	Transplacental	Unk		Not Reported
	Potassium Chloride			S	Transplacental	Unk		Not Reported

Prednisone	S	Transplacental	Unk	Not Reported
Prednisone	S	Transplacental	Unk	Not Reported
Acetaminophen (Paracetamol)	S	Transplacental	Unk	Not Reported
Calcium Carbonate	S	Transplacental	Unk	Not Reported
Folic Acid	S	Transplacental	Unk	Not Reported
Methylprednisolone	S	Transplacental	Unk	Not Reported
Methylprednisolone	S	Transplacental	Unk	Not Reported
Bisoprolol Fumarate	S	Transplacental	Unk	Not Reported
Fluconazole	S	Transplacental	Unk	Not Reported
Omeprazole	S	Transplacental	Unk	Not Reported
Hydroxychloroquine	S	Transplacental	Unk	Not Reported
Penicillin G Benzathine	S	Transplacental	Unk	Not Reported
Cefotaxime	S	Transplacental	Unk	Not Reported
Cefotaxime	S	Transplacental	Unk	Not Reported
Hydrocortisone	S	Transplacental	Unk	Not Reported
Vitamin K Nos	S	Transplacental	Unk	Not Reported
Magnesium Lactate	S	Transplacental	Unk	Not Reported
Bisulepin	S	Transplacental	Unk	Not Reported
Nadroparine	S	Transplacental	Unk	Not Reported
Privigen	S	Transplacental	Unk	Not Reported
Privigen	S	Transplacental	Unk	Not Reported
Flebogamma Dif	S	Transplacental	Unk	Not Reported
Vitamin B Complex	S	Transplacental	Unk	Not Reported
Vitamin B Complex	S	Unknown	Unk	Not Reported
Albumin	S	Transplacental	Unk	Not Reported
Ornidazole	S	Transplacental	Unk	Not Reported
Cefixime	S	Transplacental	Unk	Not Reported
Vulmizolin	S	Transplacental	Unk	Not Reported
Aminomethylbenzoic Acid	S	Transplacental	Unk	Not Reported

	Vitamin D			S	Transplacental	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17744165	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436847		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Lyrica			C	Oral			Not Reported
	Lyrica			C				Not Reported

	Prednisone	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17744175	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-JNJFOC-20200436815		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Remicade			S				Janssen
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Canakinumab			S	Subcutaneous			Not Reported
	Canakinumab			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Plaquenil /00072602/			S				Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)	
	Rituxan	S		Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S		Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S		Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17754228	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20180840374			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Limb Operation; Peripheral Swelling; Rash; Tenosynovitis; Urticaria; Wrist Surgery	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rocuronium	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Oral	Not Reported
	Rocuronium Bromide	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17758901	EXPEDITED (15-DAY)		OT	CH-PFIZER INC-2020182222		51 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Hepatic Artery Occlusion; Hepatic Infarction; Hepatic Perfusion Disorder; Hepatocellular Injury; Hypoxia; Liver Function Test Abnormal; Off Label Use; Product Use Issue	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer
	Piperacillin/Tazobactam			S	Intravenous drip	4.5 G, 3x/Day		Pfizer
	Augmentin [Amoxicillin Sodium;Clavulanate Potassium]			S	Intravenous drip	1.2 G, 4x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	800 Mg, Single		Not Reported
	Kaletra			S	Oral	400 Mg, 2x/Day		Not Reported
	Kaletra			S	Oral	400 Mg		Not Reported
	Clexane			S	Subcutaneous	40 Mg, 1x/Day		Not Reported
	Clexane			S	Subcutaneous	40 Mg, 2x/Day		Not Reported
	Clexane			S	Subcutaneous	Unk		Not Reported
	Clexane			S	Subcutaneous	40 Mg, 2x/Day		Not Reported
	Perfalgan			S	Intravenous (not otherwise specified)	1 Mg (Max 3xday; As Necessary)		Not Reported
	Ipramol			C		Unk		Not Reported
	Temesta [Lorazepam]			C		Unk		Not Reported

Tavanic	C	Unk	Not Reported
Atracurium	C	Unk	Not Reported
Fentanyl	C	Unk	Not Reported
Dormicum [Midazolam Maleate]	C	Unk	Not Reported
Phosphate [Potassium Bicarbonate;Sodium Phosphate Monobasic]	C	Unk	Not Reported
Colistin	C	Unk	Not Reported
Torasemide	C	Unk	Not Reported
Potassium	C	Unk	Not Reported
Benerva	C	Unk	Not Reported
Heparin	C	Unk	Not Reported
Solu-Medrol	C	Unk	Not Reported
Novorapid	C	Unk	Not Reported
Relistor	C	Unk	Not Reported
Novasource Gi Control	C	Unk	Not Reported
Ventoline [Salbutamol]	C	Unk (As Necessary)	Not Reported
Movicol	C	Unk (As Necessary)	Not Reported
Tobramycin	C	Unk	Not Reported
Amphotericin B	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17779489	EXPEDITED (15-DAY)		OT	NL-ADVANZ PHARMA-202004005018			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Superinfection Bacterial	Hydroxychloroquine			S	Unknown	200 Mg, Tid, Film-Coated Tablet		Concordia
	Hydroxychloroquine			S				Concordia
	Azithromycine			C		Unk		Not Reported
	Zinc Orotate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17787974	EXPEDITED (15-DAY)		DE, HO, OT	FR-PFIZER INC-2020191657			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Discomfort; Electrocardiogram Qt Prolonged; Loss Of Consciousness; Off Label Use; Product Use In Unapproved Indication; Ventricular Arrhythmia	Azithromycin			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17806676	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200517470			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17818973	EXPEDITED (15-DAY)		HO	US-ABBVIE-20K-163-3413423-00		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Anaemia; Heart Rate Increased; Heart Rate Increased; Weight Increased	Humira			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17844833	EXPEDITED (15-DAY)		HO, OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-20-025		1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia	Prednisone			S	Transplacental			Westward
	Azathioprine			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported
	Tacrolimus			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17846771	EXPEDITED (15-DAY)		DE, OT	ES-TEVA-2020-ES-1241465		86 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depressed Mood	Hidroxicloroquina (2143a)			S		Hidroxicloroquina (2143a)		Teva
	Kaletra			S				Not Reported
	Azitromicina (7019a)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17852401	EXPEDITED (15-DAY)		HO, OT	CA-UCBSA-2020021831			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Cimzia	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Monthly (Qm)	Not Reported
	Arava	S		20 Milligram	Not Reported
	Benzalkonium Chloride	S			Not Reported
	Benzalkonium Chloride	S		Unk	Not Reported
	Diphenhydramine Hydrochloride	S		Unk	Not Reported
	Phenylephrine Hydrochloride	S			Not Reported
	Boric Acid	S			Not Reported
	Diphenhydramine Hydrochloride	S			Not Reported
	Disodium Edetate	S			Not Reported
	Enbrel	S	Subcutaneous	40 Milligram, Weekly (Qw)	Not Reported
	Gold	S		Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Hydroxychloroquine Sulfate	S		200 Milligram, 2x/Day (Bid)	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	15 Milligram, Weekly (Qw)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phenylephrine Hydrochloride	S		Unk	Not Reported
	Rho D Immune Globulin	S			Not Reported
	Rituximab	S			Not Reported
	Simponi	S			Not Reported
	Sodium Borate	S		Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Tofacitinib Citrate	S	Subcutaneous	5 Milligram- 2 Every One Week	Not Reported
	Tofacitinib Citrate	S		10 Milligram-2 Every One Week	Not Reported
	Tofacitinib Citrate	S		5 Milligram-2 Every One Week	Not Reported

Xeljanz	C	Oral	5 Milligram, 2x/Day (Bid)		Not Reported
Prednisone	C				Not Reported
Lipitor	C	Oral	10 Milligram, Once Daily (Qd)		Not Reported
Ibuprofen	C	Oral	400 Milligram		Not Reported
Celebrex	C	Oral	400 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17852411	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042938			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligarm Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17852544	EXPEDITED (15-DAY)		DE	IT-BEH-2020117974		71 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Human Immunoglobulin (Inn)			S	Intravenous (not otherwise specified)	0.4 Gram Per Kilogram, Qd		Csl Behring
	Lopinavir + Ritonavir			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17852844	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609744			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Simponi			C				Not Reported
	Prednisone			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17852846	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202005005835			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Covid-19; Odynophagia; Off Label Use; Pyrexia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17852848	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202005005790			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Renal Colic	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	1 Dosage Form, Qd		Concordia

	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Oral	1 Df, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17852850	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202005005786			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg,Film-Coated Tablet		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17852855	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202005005836			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Covid-19; Myalgia; Off Label Use; Rhinorrhoea	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	1 Dosage Form, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17852903	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201701-000493			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Depression; Drug Ineffective; Finger Deformity; Foot Operation; Headache; Hyperhidrosis; Joint Swelling; Nausea; Night Sweats; Osteoarthritis; Palpitations; Rheumatoid Arthritis; Therapeutic Response Decreased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly 50 Mg,Qw		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Cimzia			S	Unknown	200 Mg (Qow)		Not Reported
	Humira			S	Unknown	40 Mg (Qow)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Unk		Not Reported

Methotrexate Sodium	S	Oral	25 Mg, Weekly (Qw)		Not Reported
Methotrexate Sodium	S	Oral	17.5 Mg, Weekly (Qw)		Not Reported
Methotrexate Sodium	S	Oral	15 Mg, Weekly (Qw)		Not Reported
Leucovorin	C		Unk		Not Reported
Vitamin D	C		Unk		Not Reported
Coversyl	C		Unk		Not Reported
Ergocalciferol	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17853277	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2608694			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme Increased; Ileus; Intestinal Obstruction; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapy Non-Responder; Wheelchair User	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17853750	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043107		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Pain; Red Blood	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported

Cell Sedimentation Rate Abnormal; Treatment Failure	Anakinra	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported
	Methotrexate	C	Oral	25 Milligram, 2 Every 1 Week	Not Reported
	Prednisone	C	Unknown	30 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17853844	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043063			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Prednisone		C	Unknown	2 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17853872	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-027229		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hypertriglyceridaemia; Rhabdomyolysis	Azithromycin			S	Oral	Unk		Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17853956	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202005005079			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Z-Pak			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17853974	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202005005087			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17854012	EXPEDITED (15-DAY)		OT	AR-GLAXOSMITHKLINE-AR2020AMR089296		54 YR	Female	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Headache; Muscular Weakness; Paraparesis; Ulcer; Walking Aid User	Belimumab	S	400 Mg, Z, Monthly	Glaxosmithkline
	Omeprazole	S	Unk	Glaxosmithkline
	Vitamin D3	S	Unk	Glaxosmithkline
	Mycophenolic Acid	S	Unk	Not Reported
	Hydroxychloroquine	S	Unk	Not Reported
	Methylprednisone Dose Pack	S	360 Unk	Not Reported
	Ibandronate	S	Unk	Not Reported
	Pregabaline	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17854014	EXPEDITED (15-DAY)		OT	AR-GLAXOSMITHKLINE-AR2020AMR090165		52 YR	Female	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Dna Antibody Positive; Erythema; Fatigue; Leukopenia; Mouth Ulceration; Muscle Injury; Nasal Ulcer; Pericardial Effusion; Pleural Effusion; Proteinuria; Uveitis; Weight Decreased	Benlysta			S		920 Mg, Z, Monthly		Glaxosmithkline
	Vitamin D			S		Unk		Glaxosmithkline
	Ranitidine			S		Unk		Glaxosmithkline
	Folic Acid			S		Unk		Glaxosmithkline
	Azathioprine			S		Unk		Glaxosmithkline
	Mycophenolate Mofetil			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Methylprednisone Dose Pack			S		Unk		Not Reported
	Isoniazid			S		Unk		Not Reported
	Trimethoprim-Sulfamethoxazole			S		Unk		Not Reported
	Methotrexate			S		20 Mg, Z, Weekly		Not Reported
	Naproxene			S		Unk		Not Reported
	Angiotensin-Converting Enzyme Inhibitor			S		Unk		Not Reported
	Enalapril			S		Unk		Not Reported
	Influenza Vaccine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17854051	EXPEDITED (15-DAY)		OT	CA-ROCHE-2611170			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Demyelination; Dermatomyositis; Drug Intolerance; Fatigue; Mental Disorder; Muscle Injury; Myalgia; Off Label Use; Product Use In Unapproved Indication; Pruritus; Rash	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17854123	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-027235		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Azithromycin			S	Oral	Unk		Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Two Times A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17854196	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606540			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

Erythematosus	Fosamax	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17854253	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-2160			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Meningitis; Pain; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17854357	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606672		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17854527	EXPEDITED (15-DAY)		DS	GB-ACCORD-183964		83 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Hypotension; Off Label Use	Hydroxychloroquine			S				Not Reported
	Mirabegron			C				Not Reported
	Amoxicillin			C				Not Reported
	Digoxin			C				Not Reported
	Paracetamol			C				Not Reported
	Adcal-D3			C				Not Reported
	Bisoprolol			C				Not Reported
	Omeprazole			C				Not Reported
	Dabigatran/Dabigatran Etexilate			C				Not Reported

	Alendronate Sodium/Alendronic Acid	C		Not Reported
	Atorvastatin	C		Not Reported
	Gabapentin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17854547	EXPEDITED (15-DAY)		OT	MT-PFIZER INC-2020214578		13 YR	Male	MLT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Immunosuppression; Off Label Use; Product Use In Unapproved Indication	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Ibuprofen			C		Unk (Regular)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17854611	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202005005090			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S		Unk		Concordia
	Methotrexate			S				Not Reported
	Xeljanz Xr			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17854624	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-027228		35 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia	Azithromycin			S	Oral	Unk		Aurobindo
	Kaletra			S	Oral	2 Dosage Form, Two Times A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17854633	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-027233		33 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia; Liver Disorder	Azithromycin			S	Oral	Unk		Aurobindo
	Ceftriaxona			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17855313	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020215777		64 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypofibrinogenaemia; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 2x/Day (Every 12 Hours)		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 G, 1x/Day		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17855319	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1053154		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Function Abnormal; Off Label Use	Azithromycin			S	Oral	500 Mg Cada 24h		Not Reported
	Azithromycin			S				Not Reported
	Ceftriaxona /00672201/			S	Unknown	No Especificada		Mylan
	Ceftriaxona /00672201/			S				Mylan

	Hidroxicloroquina /00072601/	S	Oral	400 Mg C/12 Horas Seguido De 200 Mg C/12 Horas	Mylan
	Hidroxicloroquina /00072601/	S			Mylan
	Lopinavir/Ritonavir	S	Oral	400 Mg C/12 Horas, 120 Tablets (Blister)	Mylan
	Lopinavir/Ritonavir	S			Mylan
	Atacand	C		28 Tablet	Mylan
	Parizac /00661201/	C		20 Capsules	Mylan
	Carduran Neo	C		28 Tablets	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17855326	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1053156		64 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypofibrinogenaemia; Off Label Use	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Hidroxicloroquina Sulfato			S	Oral	200 Milligram, Bid		Mylan
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	1 Gram, Qd		Mylan
	Tocilizumab			S	Intravenous (not otherwise specified)	400 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17855483	EXPEDITED (15-DAY)		OT	CA-ROCHE-2607377		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Laboratory Test Abnormal	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Folic Acid	C	Unknown	Not Reported
	Hyzaar	C	Unknown	Not Reported
	Venlafaxine Hydrochloride	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17855560	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608742		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

	Apo-Leflunomide	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17855708	EXPEDITED (15-DAY)		DS	CA-ROCHE-2606600		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Cortisone			S	Oral			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Cortisone Acetate			S	Oral			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported

Diclofenac Sodium	S	Unknown	Not Reported
Diclofenac Sodium	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Folic Acid	S	Oral	Not Reported
Folic Acid	S	Oral	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Fosamax	S	Oral	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Leflunomide	S	Oral	Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate Sodium	S	Subcutaneous	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Paracetamol	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Not Reported

Phthalylsulfathiazole	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sarilumab	S	Unknown	Not Reported
Sarilumab	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Not Reported
Stelara	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Subcutaneous	Not Reported
Topicort [Desoximetasone]	S	Oral	Not Reported
Topicort [Desoximetasone]	S	Subcutaneous	Not Reported
Topicort [Desoximetasone]	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S		Not Reported
Tofacitinib Citrate	S	Unknown	Not Reported
Salazopyrin	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17855717	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1242988		52 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva

Tocilizumab (8289a)	S	Intravenous (not otherwise specified)	600 Milligram Daily;		Not Reported
Ivermectina (7778a)	S	Oral	12 Mg, 4 Cp Day		Not Reported
Enoxaparina (2482a)	S	Intravenous (not otherwise specified)	40 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17855762	EXPEDITED (15-DAY)		OT	CA-ROCHE-2611746			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Joint Swelling; Leukopenia; Off Label Use; Rash; Visual Impairment	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17855878	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1053459		62 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Off Label Use; Pruritus; Rash	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Roactemra			S		1 Dosage Form, Qd		Mylan
	Clexane			S	Subcutaneous	8000 Kilo-International Unit, Qd		Mylan
	Plaquenil /00072603/			S	Oral	2 Dosage Form, Qd		Mylan

	Fidato	S	Intravenous (not otherwise specified)	1 Dosage Form, Qd	Mylan
	Kaletra	S	Oral	4 Dosage Form, Qd	Mylan
	Urbason /00049602/	S	Intravenous (not otherwise specified)	1 Dosage Form, Qd	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17855942	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606497			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Bupropion			C				Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856027	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606575			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain;	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856045	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042318			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Loss Of Personal	Orencia			S	Intravenous (not otherwise specified)	250 Milligram (1 Every 1 Month)		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Qwk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Q2wk (Unknown Dosage Form)		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram (4 Every 1 Week)		Not Reported

Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Enbrel		S	Subcutaneous	25 Unk	Not Reported
	Hydroxychloroquine		S	Oral	5 Milligram/Kilogram, Qd	Not Reported
	Immune Globulin (Immunoglobulins Nos)		S	Intravenous (not otherwise specified)	70 Gram	Not Reported
	Infliximab		S	Subcutaneous	5 Milligram, Qwk	Not Reported
	Infliximab		S	Unknown	3 Milligram/Kilogram	Not Reported
	Methotrexate		S	Subcutaneous	15 Milligram/Kilogram, Qwk	Not Reported
	Naproxen		S	Unknown		Not Reported
	Prednisone		S	Oral	3 Milligram	Not Reported
	Prednisone		S	Oral	5 Milligram, Bid	Not Reported
	Sulfasalazine		S	Oral	250 Milligram	Not Reported
	Triamcinolone		S	Unknown		Not Reported
	Triamcinolone Hexacetonide		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856059	EXPEDITED (15-DAY)		OT	CA-ROCHE-2611040			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Neutropenia; White Blood Cell Count Decreased	Rituximab			S	Unknown	4.0 Years		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856207	EXPEDITED (15-DAY)		DE	FR-FRESENIUS KABI-FK202005528		86 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Treatment Failure	Azithromycin (Manufacturer Unknown)	S	Unknown		Fresenius Medical Care
	Azithromycin (Manufacturer Unknown)	S	Unknown		Fresenius Medical Care
	Hydroxychloroquine	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856253	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042245		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Baclofen			C	Unknown	Unk		Not Reported
	Estradiol			C	Unknown	Unk		Not Reported
	Furosemide			C	Unknown	Unk		Not Reported
	Levaquin			C	Unknown	Unk		Not Reported
	Valsartan			C	Unknown	Unk		Not Reported
	Xalatan			C	Ophthalmic	Unk		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856279	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200535394		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease; Drug Ineffective; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S				Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856297	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200535392		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Wellbutrin			C	Unknown	Extended Release Tablet		Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856321	EXPEDITED (15-DAY)		OT	CA-ROCHE-2613036			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Rivotril			S	Unknown			Not Reported
	Zopiclone			S	Unknown			Not Reported
	Zantac			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Nifedipine			S	Unknown			Not Reported
	Morphine Hydrochloride			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cefixime			S	Unknown			Not Reported
	Bisoprolol Fumarate			S	Unknown			Not Reported
	Azathioprine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856322	EXPEDITED (15-DAY)		OT	CA-ROCHE-2612975			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Rivotril			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Cefixime			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Oral			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Morphine Hydrochloride	S	Unknown	Not Reported
	Nifedipine	S	Unknown	Not Reported
	Pantoprazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Zantac	S	Unknown	Not Reported
	Zopiclone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856381	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200535384			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept /01275102/			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Piroxicam	C			Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856382	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200535383		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Fatigue; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)	3 Mg		Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Ciclosporin			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S				Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine		S	Oral	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856403	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200535381			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Drug Ineffective; Drug Intolerance; Gait Disturbance; Gastrooesophageal Reflux Disease; Hepatic Enzyme Increased; Hypokinesia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Stiffness; Nausea; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Delayed	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Tylenol 8 Hr Arthritis Pain			C	Unknown	Extended Release		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856406	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200535379		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspepsia; Liver Function Test Increased; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856407	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200535380			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Nausea	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856413	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200535375		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Joint Swelling; Pneumonia; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Orencia			S				Not Reported
	Plaquenil /00072602/			S				Not Reported
	Infliximab			S				Not Reported
	Rituximab			S				Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Cephalexin /00145501/			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856414	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200535374			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Simponi			S	Intravenous (not otherwise specified)			Janssen
	Simponi Iv			S	Intravenous (not			Janssen

			otherwise specified)	
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S		Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Prednisone	S		Not Reported
	Prednisone	S		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856415	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200535378			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Synovitis; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Amlodipine	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856591	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-036909		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Palpitations; Stress	Abatacept			S	Intravenous (not otherwise specified)	500 Milligram, Q4wk		Bristol Myers Squibb
	Hydroxychloroquine			S	Oral	200 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown	Unk		Not Reported
	Vitamin D [Vitamin D Nos]			C	Unknown	Unk		Not Reported
	Calcium			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856622	EXPEDITED (15-DAY)		OT	CA-SA-2020SA137771			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatotoxicity; Mycobacterium Tuberculosis Complex Test Positive	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Rosuvastatin Calcium			S		Unk		Not Reported
	Plaquenil			S		200 Mg, Bid		Sanofi
	Plaquenil			S		200 Mg, Qd		Sanofi
	Prednisone			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Nexium [Esomeprazole Sodium]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856792	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043533			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Milligram, 1 Every 1 Week		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856832	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200537327		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Tuberculin Test Positive	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Xeljanz	S	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856875	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200537323		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported

Darifenacin Hydrobromide	C	Unknown	Not Reported
Dexamethasone	C	Unknown	Not Reported
Dexamethasone	C	Intramuscular	Not Reported
Dilaudid	C	Intramuscular	Not Reported
Diphenhydramine Hydrochloride	C	Intramuscular	Not Reported
Furosemide	C	Unknown	Not Reported
Hydromorphone	C	Unknown	Not Reported
Kadian	C	Unknown	Not Reported
Loperamide	C	Unknown	Not Reported
Norflex /00018303/	C	Unknown	Not Reported
Omnaris	C	Unknown	Not Reported
Oxyneo	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Restasis	C	Unknown	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Not Reported
Synthroid	C	Unknown	Not Reported
Triamcinolone Acetonide	C	Intra-articular	Not Reported
Trimethoprim	C	Unknown	Not Reported
Urispas	C	Unknown	Not Reported
Vagifem	C	Vaginal	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856877	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200537320			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Steatosis; Synovitis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Humira	S	Subcutaneous			Not Reported
Hydroxychloroquine	S	Unknown	Duration: 10 Months		Not Reported
Leflunomide	S	Unknown			Not Reported
Methotrexate	S	Unknown	Duration: 7 Years		Not Reported
Orencia	S	Unknown			Not Reported
Actemra	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856930	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200536754		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Darifenacin			C				Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Diphenhydramine			C	Unknown			Not Reported
	Loperamide			C	Unknown			Not Reported
	Norflex			C	Unknown			Not Reported
	Omnaris			C	Unknown			Not Reported
	Pantoprazole Sodium Anhydrous			C	Unknown			Not Reported
	Plantago Ovata			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported

	Vagifem			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856967	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606144			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Headache; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Stomatitis; Tinnitus; Treatment Failure	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17857193	EXPEDITED (15-DAY)		OT	NVSC2020CA153343			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pneumonia; Rheumatoid Arthritis; Synovitis	Cosentyx			S	Unknown			Novartis
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17857388	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043555		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Systemic Lupus Erythematosus	Orencia	S	Intravenous (not otherwise specified)	Unk	Bristol Myers Squibb
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cetirizine	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17857390	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043618		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Etanercept			S	Subcutaneous	Unk		Not Reported

Humira	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Infliximab	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Tocilizumab	S	Unknown	Unk		Not Reported
Methotrexate	C	Unknown	25 Milligram		Not Reported
Prednisone	C	Unknown	30 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17857394	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043525			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17857410	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043499			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17857427	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043537			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17857451	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043185			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram		Not Reported

Daily Activities; Pain; Peripheral Swelling	Enbrel		S	Unknown	50 Milligram	Not Reported
	Humira		S	Subcutaneous	20 Milligram	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	200 Milligram, Bid	Not Reported
	Methotrexate		S	Subcutaneous	20 Milligram	Not Reported
	Prednisone		S	Oral	5 Milligram	Not Reported
	Sulfasalazine		S	Unknown	1000 Gram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17858727	DIRECT	Y	DE			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17858758	DIRECT	Y	DE			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Electrocardiogram Qt Prolonged; Sudden Death	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	12137035	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-014026			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture;	Orencia			S	Unknown	1 Df, Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Milligram		Not Reported

Intervertebral Disc Disorder; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Methotrexate Sodium	S	Unknown	15 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	10 Mg, Qd	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	10 Mg, Qd	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	15 Milligram	Not Reported
	Methotrexate	S	Unknown	20 Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	12321013	EXPEDITED (15-DAY)		OT	CA-ROCHE-1745426		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug	Actemra			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single Use As Prefilled Syring		Not Reported

Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Knee Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Desoximetasone	S	Unknown	Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Acetaminophen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	12766798	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076609		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulphate			S	Oral	400 Milligram, Qd		Not Reported
	Methotrexate			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Milligram, Qwk		Not Reported
	Hydroxychloroquine Phosphate			S	Oral	400 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Naprosyn [Naproxen]			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	12913793	EXPEDITED (15-DAY)		DS, LT, OT	CA-BRISTOL-MYERS		43 YR	Female	CAN

SQUIBB COMPANY-
BMS-2016-091772

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Paracetamol			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram, Qd		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Oral	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Topical	25 Milligram		Not Reported
	Cortisone Acetate			S	Oral	25 Milligram		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Cutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported

Failure; Wound	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	500 Milligram	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Sunconjunctival	Unk	Not Reported
	Humira	S	Sunconjunctival	40 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Urethral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	1 Gram, Bid	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	Unk, Qd	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram, Qd	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	10 Milligram	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravesical	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported

Sulfasalazine	S	Oral	500 Mg, Unk	Not Reported
Sulfasalazine	S	Oral	1 G, Bid	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form	Not Reported
Xeljanz	S	Unknown	5 Milligram, Q12h	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
Zyrtec [Cetirizine Hydrochloride]	S	Unknown	10 Milligram	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Cortisone	S	Oral	25 Milligram	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	1 Milligram	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
Apo Hydroxyquine	S	Unknown	Unk	Not Reported
Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
Pseudoephedrine Hcl	S	Unknown	25 Milligram	Not Reported
Kevzara	S	Unknown	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous	Unk	Not Reported

Topicort [Hydrocortisone Acetate]	S	Oral	Unk	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	25 Milligram	Not Reported
Etanercept	S	Unknown	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Golimumab	S	Subcutaneous	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Unknown	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Oral	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Oral	10 Milligram	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Prednisone	S	Unknown	5 Unk	Not Reported
Prednisone	S	Unknown	1 Milligram	Not Reported
Prednisone	S	Unknown	40 Milligram	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
Cetirizine	S	Unknown	Unk	Not Reported
Cetirizine	S	Unknown	10 Milligram	Not Reported
Cetirizine	S	Oral	10 Milligram	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported

Acetaminophen	S	Unknown	Unk	Not Reported
Apo-Folic Acid	S	Unknown	5 Milligram	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Cortisone Acetate	S	Oral	25 Milligram	Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Diclofenac	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	25 Milligram	Not Reported
Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
Sulfasalazine	S	Oral	Unk Unk, Bid	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Folic Acid	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	5 Milligram	Not Reported
Folic Acid	S	Unknown	1 Milligram	Not Reported
Folic Acid	S	Oral	25 Milligram	Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Cortisone	S	Unknown	25 Milligram	Not Reported
Alendronate Sodium	S	Oral	Unk	Not Reported
Alendronate Sodium	S	Unknown	Unk	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Winpred	S	Oral	Unk	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk	Not Reported
Rituximab	S	Intravenous drip	Unk	Not Reported
Atasol [Paracetamol]	C	Unknown	Unk	Not Reported

Salazopyrin	C	Unknown	Unk		Not Reported
Tofacitinib Citrate	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Zyrtec-D	C	Unknown	Unk		Not Reported
Ibuprofen	C	Unknown	Unk		Not Reported
Lisinopril	C	Unknown	Unk		Not Reported
Vitamin D3	C	Unknown	Unk		Not Reported
Diclofenac	C	Unknown	50 Milligram		Not Reported
Leflunomide	C	Oral			Not Reported
Prednisolone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	13006742	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP015239		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity;	Alendronate			S	Unknown	70 Mg, Q.Wk.		Apotex
	Alendronate			S				Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Oral	200 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Apo-Leflunomide			S	Oral	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Unk		Apotex

Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Mg, B.I.Wk.	Not Reported
	Enbrel	S	Unknown	50 Mg, Q.Wk.	Not Reported
	Enbrel	S	Unknown	25 Mg, Q.Wk.	Not Reported
	Enbrel	S	Unknown	25 Mg, Unk	Not Reported
	Enbrel	S	Unknown	50 Mg, Q.Wk.	Not Reported
	Enbrel	S	Unknown	25 Mg, Q.O.Wk.	Not Reported
	Enbrel	S	Unknown	25 Mg, B.I.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk, Cyclical	Not Reported
	Humira	S	Subcutaneous	40 Mg, 1 Every 2 Week	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Unk, Unk	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	12.5 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Unknown	12 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Q.Wk.	Not Reported
	Orencia	S	Unknown	780 Mg, Q.Wk.	Not Reported
	Orencia	S	Unknown	780 Mg, Q.Wk.	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	760 Mg, Q.Wk.	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk (Therapy Duration 365 Unspecified Unit)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not	1000 Mg, Bid	Not Reported

		otherwise specified)		
Rituxan	S	Unknown	1000 Mg, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Tocilizumab	S	Unknown	360 Mg, Q.M.T.	Not Reported
Tocilizumab	S	Unknown	680 Mg, Q.M.T.	Not Reported
Tocilizumab	S	Unknown	680 Mg, 1 Every 4 Weeks	Not Reported
Tocilizumab	S	Unknown	360 Mg, Q.M.T.	Not Reported
Actemra	S	Unknown	360 Mg, Q.M.T.	Not Reported
Actemra	S	Unknown	680 Mg, Q.M.T.	Not Reported
Actemra	S	Unknown	2.68 Mg, 1 Every 4 Weeks	Not Reported
Actemra	S	Unknown	2.68 Mg, 1 Every 4 Weeks	Not Reported
Actemra	S	Unknown	680 Mg, Q.M.T.	Not Reported
Methotrexate	S	Oral	10 Mg, Q.Wk.	Not Reported
Methotrexate	S	Oral	12.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Oral	10 Mg, 1 Every 4 Weeks	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituximab	S	Unknown	1000 Mg, Bid	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Qd	Not Reported
Sulfasalazin	S	Unknown	500 Mg, Unk	Not Reported
Myochrysine	S	Parenteral	50 Mg, Q.M.T.	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Q.M.T.	Not Reported
Myochrysine	S	Intramuscular	25 Mg, Q.Wk.	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Unk	Not Reported
Adalimumab	S	Subcutaneous	40 Mg, Unk	Not Reported
Methotrexate	S	Subcutaneous	10 Mg, Q.Wk.	Not Reported

Methotrexate	S	Unknown	17.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	12 Mg, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Subcutaneous	70 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	12 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	15.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	15 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	10 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	12.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	12.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	15 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	17.5 Mg, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Subcutaneous	10 Mg, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Unknown	15 Mg, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Unknown	12.5 Mg, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Unknown	12 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	12 Mg, Unk	Not Reported
Alendronic Acid	S	Unknown	70 Mg, Q.Wk.	Not Reported
Arava	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Unknown	360 Mg, Q.M.T.	Not Reported
Simponi	S	Subcutaneous	680 Mg, Q.M.T.	Not Reported
Etanercept	S	Unknown	50 Mg, Q.Wk.	Not Reported
Etanercept	S	Unknown	25 Mg, Unk	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Sulfasalazine	S	Intravenous (not otherwise specified)	500 Mg, Unk	Not Reported

	Sulfasalazine	S	Unknown	Unk	Not Reported
	Ciclosporin	C	Unknown	150 Mg, Qd	Not Reported
	Prednisone	C	Unknown	10 Mg, Qd	Not Reported
	Prednisone	C	Unknown	10 Mg, Qd	Not Reported
	Prednisone	C	Unknown	10 Mg, Q.2h.	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Xeljanz	C	Unknown	5 Mg, Bid	Not Reported
	Alendronate Sodium	C	Subcutaneous	70 Mg, Q.Wk.	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Prednisolone	C	Unknown	10 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	13067408	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-1871510		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 365.0		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fosamax			S	Oral			Not Reported
	Fosamax			S	Unknown			Not Reported

Related Reaction; Injury; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Pregnancy; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Fosamax	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Oral		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Apo-Prednisone	S			Not Reported
	Apo Hydroxyquine	S	Unknown		Not Reported
	Cortisone	S	Unknown		Not Reported
	Paracetamol	S	Unknown		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Stelara	S	Unknown		Not Reported
	Sulfathalidine	S	Unknown		Not Reported
	Sulfathalidine	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cimzia	S	Unknown		Not Reported
	Cimzia	S	Unknown		Not Reported

Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Cortisone Acetate	S	Topical	Not Reported

Cortisone Acetate	S	Oral	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Topicort [Desoximetasone]	S	Cutaneous	Not Reported
Topicort [Desoximetasone]	S	Oral	Not Reported
Topicort [Desoximetasone]	S	Other	Not Reported
Topicort [Desoximetasone]	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Diclofenac	S	Unknown	Not Reported
Diclofenac	S	Unknown	Not Reported
Cetirizine	S	Unknown	Not Reported
Diclofenac Sodium	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	13254993	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP006561		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Crohn'S Disease; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue;	Fentanyl			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Gabapentin			S	Oral	100 Mg, Bid		Apotex
	Actemra			S	Intravenous (not otherwise specified)	488 Mg,Once Every Four Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488 Mg, Q.M.T.		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.I.W		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Bid		Not Reported

Gastrointestinal Disorder; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate	S	Subcutaneous	Unk Unk, Q.Wk.	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Once Every 4 Weeks	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Q.M.T.	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	75 Mg, Once Every 4 Weeks	Not Reported
	Orencia	S	Subcutaneous	Unk, Q.Wk.	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2.5 G, Qd	Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Myochrysine	S	Intramuscular	50 Mg, Unk	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
	Actonel	C	Unknown	36 Mg, Q.Wk.	Not Reported
	Calcium	C	Unknown		Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	Unk, Qd	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg, Qd	Not Reported
	Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported
	Gabapentin	C	Oral	100 Mg, Bid	Not Reported
	Genteal /00445101/	C	Unknown		Not Reported
	Lomotil /00034001/	C	Unknown	2.5 Mg, Unk	Not Reported
	Nasonex	C	Unknown	2 Df, Bid	Not Reported
	Nexium /01479302/	C	Unknown	40 Mg, Bid	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Mg, Q.H.	Not Reported
	Omega 3 /01334101/	C	Unknown	1200 Mg, Bid	Not Reported
	Prednisone	C	Unknown	5 Mg, Qd	Not Reported
	Prednisone	C	Unknown	5 Mg, 1 Every 2 Hours	Not Reported
	Trazodone Hydrochloride	C	Oral	50 Mg, Q.H.	Not Reported
	Tylenol /00020001/	C	Oral	1000 Mg, Unk	Not Reported

Vitamin D /00107901/	C	Unknown			Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Mg, Bid		Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Mg, Bid		Not Reported
Acetaminophen	C	Oral	1000 Mg, Qd		Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	Unk		Not Reported
Omega-3 Fatty Acids	C	Unknown	Unk		Not Reported
Risedronate Sodium	C	Unknown	36 Mg, Q.Wk.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	13611477	NON-EXPEDITED			US-PFIZER INC-2017243599			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Unknown
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	14263210	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2017AP022159		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Levofloxacin			S	Unknown	Unk		Apotex
	Norfloxacin			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Bisoprolol			S	Unknown	Unk		Not Reported
	Erythro-Base			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Celecoxib			S	Oral	200 Mg, Qd		Apotex
	Erythromycin			S	Unknown	Unk		Not Reported

Metronidazole	S	Unknown	5 Mg, Unk		Not Reported
Ceclor	S	Unknown	Unk		Not Reported
Arava	S	Unknown	Unk		Not Reported
Arthrotec	S	Unknown	Unk		Not Reported
Celebrex	S	Oral	200 Mg, Qd		Not Reported
Demerol	S	Unknown	Unk		Not Reported
Erythromycin Estolate	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	400 Mg, Unk		Not Reported
Lyrica	S	Unknown	Unk		Not Reported
Meperidine Hydrochloride	S	Unknown	Unk		Not Reported
Methotrexate Sodium	S	Oral	20 Mg, Q.Wk.		Not Reported
Methotrexate Sodium	S	Unknown	Unk		Not Reported
Metronidazole	S	Unknown	Unk		Not Reported
Plaquenil /00072602/	S	Oral	400 Mg, Qd		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	14502886	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007063		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Disability; Disease Recurrence; Drug Ineffective; Dyspnoea; Impaired Work Ability; Infection; Insomnia; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased;	Abatacept			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qd		Not Reported
	Arava			S	Oral	200 Milligram, Qd		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Rash; Rheumatoid Arthritis; Skin Mass; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapeutic Product Effect Decreased; Therapy Non-Responder	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qmo	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	200 Milligram, Qd	Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone Acetate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Tofacitinib Citrate	S	Oral	5 Milligram,2every1day	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
	Apo-Hydroxyquine	S	Oral	400 Milligram, Qd	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	2 Gram, Q6mo	Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Actonel	C	Unknown		Not Reported
	Sulfasalazine	C	Oral	Unk	Not Reported
	Sulfasalazine	C	Oral	500 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	14909761	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Breast Cancer; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Infection; Joint Swelling; Loss Of Consciousness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown	8 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported
	Leflunomide			S	Unknown	10 Milligram		Not Reported
	Leflunomide			S	Oral	20 Milligram		Not Reported
	Methotrexate			S	Endocervical	25 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	15 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	25 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral	50 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

	Apo-Hydroxyquine	S	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported
	Simponi	C	Unknown			Not Reported
	Meloxicam	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	15374470	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP020179			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Acetaminophen			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	2000 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown	Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	25 Mg, Q.Wk.		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	15615412	EXPEDITED (15-DAY)		DS, LT, OT	CA-APOTEX-2016AP016280			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Hypertension; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis;	Apo Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Apo Folic Acid			S	Unknown	15 Mg, Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Apotex
	Apo Prednisone Tab 1mg Usp			S	Unknown	Unk		Apotex
	Diclofenac			S	Unknown	Unk		Apotex
	Diclofenac			S	Unknown	50 Mg, Unk		Apotex
	Prednisone			S	Unknown	400 Mg, Unk		Apotex
	Prednisone			S	Unknown	1 Mg, Unk		Apotex
	Prednisone			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Urethral	400 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	Unk Unk, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk Unk, Qd		Apotex
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Cetirizine			S	Unknown	Unk		Apotex
	Cetirizine			S	Oral	10 Unk, Unk		Apotex
	Cetirizine			S	Unknown	10 Mg, Qd		Apotex
	Cetirizine			S	Unknown	25 Mg, Unk		Apotex
	Apo-Prednisone			S	Unknown	1 Mg, Unk		Apotex
	Apo-Prednisone			S	Unknown	5 Mg, Unk		Apotex
	Apo-Prednisone			S	Oral	Unk		Apotex
	Acetaminophen			S	Unknown	Unk		Apotex

Pregnancy; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wheezing; Wound	Folic Acid	S	Unknown	1 Unk, Unk	Not Reported
	Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	1 Mg, Unk	Not Reported
	Folic Acid	S	Oral	25 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	500 Mg, Unk	Not Reported
	Folic Acid	S	Oral	5 Mg, Unk	Not Reported
	Folic Acid	S	Oral	1 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Apotex
	Leflunomide	S	Oral	Unk	Apotex
	Alendronate	S	Oral	Unk	Apotex
	Actemra	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Oral	20 Mg, Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	400 Mg, Unk	Not Reported
	Sulfasalazine	S	Oral	1 G, Bid	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Oral	1 Df, Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	1 G, Bid	Not Reported
	Sulfasalazine	S	Oral	1 G, Qd	Not Reported
	Sulfasalazine	S	Oral	1000 Mg, Bid	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported

Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Cutaneous	Unk	Not Reported
Desoximetasone	S	Unknown	25 Mg, Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Fosamax	S	Unknown	Unk, Intra Corpus Cavernosum	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Sunconjunctival	40 Mg, Unk	Not Reported
Humira	S	Sunconjunctival	Unk	Not Reported
Methotrexate	S	Intra-arterial	25 Mg, Unk	Not Reported
Methotrexate	S	Intra-arterial	25 Unk, Unk	Not Reported
Methotrexate	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Intracardiac	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Oral	500 Mg, Unk	Not Reported
Phthalylsulfathiazole	S	Oral	1000 Mg, Bid	Not Reported
Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
Plaquenil /00072602/	S	Oral	Unk Unk, Qd	Not Reported
Plaquenil /00072602/	S	Unknown	400 Mg, Unk	Not Reported
Plaquenil /00072602/	S	Oral	400 Mg, Qd	Not Reported
Plaquenil /00072602/	S	Oral	Unk	Not Reported
Plaquenil /00072602/	S	Oral	1 Df, Qd	Not Reported

Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravesical	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Reactine /00884302/	S	Unknown	Unk	Not Reported
Reactine /00884302/	S	Unknown	10 Mg, Unk	Not Reported
Cortisone	S	Unknown	25 Mg, Unk	Not Reported
Cortisone	S	Topical	25 Mg, Unk	Not Reported
Topicort /00028604/	S	Subcutaneous	Unk	Not Reported
Topicort /00028604/	S	Cutaneous	Unk	Not Reported
Topicort /00028604/	S	Oral	Unk	Not Reported
Topicort /00028604/	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Pseudoephedrin Hydrochloride	S	Unknown	25 Mg, Unk	Not Reported
Pseudoephedrin Hydrochloride	S	Unknown	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Mg, Bid	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Mg, Qd	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	25 Mg, Unk	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	10 G, Unk	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Unk	Not Reported

Cortisone	S	Oral	Unk	Not Reported
Cortisone	S	Oral	25 Mg, Unk	Not Reported
Cortisone	S	Unknown	25 Mg, Unk	Not Reported
Cortisone	S	Unknown	Unk	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Cortisone Acetate	S	Oral	25 Mg, Unk	Not Reported
Cortisone Acetate	S	Topical	25 Mg, Unk	Not Reported
Cortisone Acetate	S	Oral	25 Mg, Unk	Not Reported
Etanercept	S	Unknown	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Subcutaneous	Unk	Not Reported
Topicort /00028604/	S	Subcutaneous	Unk	Not Reported
Topicort /00028604/	S	Oral	Unk	Not Reported
Topicort /00028604/	S	Unknown	Unk	Not Reported
Topicort /00028604/	S	Other	Unk	Not Reported
Zyrtec /00884302/	S	Unknown	10 Mg, Unk	Not Reported
Methotrexate	S	Oral	25 Mg, Unk	Not Reported
Methotrexate	S	Oral	20 Mg, Qd	Not Reported
Methotrexate	S	Oral	1 G, Bid	Not Reported
Methotrexate	S	Oral	25 Mg, Qd	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	25 Mg, Unk	Not Reported
Methotrexate	S	Oral	25 Mg, Unk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Oral	1 Df, Qd	Not Reported

Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	20 Mg, Q.Wk.	Not Reported
Tofacitinib Citrate	S	Unknown	5 Mg, Bid	Not Reported
Folic Acid	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	400 Mg, Qd	Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
Actemra	S	Oral	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Hydrocortisone	S	Oral	Unk	Not Reported
Sulfasalazine	S	Subcutaneous	1 G, Qd	Not Reported
Sulfasalazine	S			Not Reported
Salazopyrine	S	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Ibuprofen	C	Unknown	Unk	Not Reported
Atasol /00020001/	C	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Lisinopril	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Zyrtec-D	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	15630696	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105381		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal	Orencia			S	Unknown			Bristol Myers Squibb

Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Fatigue; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rheumatoid Arthritis; Rotator Cuff Syndrome; Swelling; Therapeutic Response Decreased; Tongue Ulceration; Tooth Infection; Treatment Failure	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Nystatin	S	Unknown		Not Reported
	Nystatin	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Indometacin	C	Unknown	Unk	Not Reported
	Tramadol	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	15694039	EXPEDITED (15-DAY)		HO, OT	US-DRREDDYS-USA/USA/18/0105952		1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia	Tacrolimus			S	Transplacental			Not Reported
	Tacrolimus			S				Not Reported
	Azathioprine			S	Transplacental			Not Reported
	Azathioprine			S				Not Reported
	Prednisone			S	Transplacental			Not Reported
	Prednisone			S				Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported
	Hydroxychloroquine			S				Not Reported
	Betamethasone			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	15935428	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2657038-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			C	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	16296936	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2019GSK081498		68 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Lower; Asthma; Atelectasis; Blood Disorder; Blood Immunoglobulin E Increased; Blood Test Abnormal; Bronchial Wall Thickening; Bronchiolitis; Condition Aggravated; Cough; Dysphonia; Dyspnoea; Eosinophil Count Increased; Eosinophilic Granulomatosis With Polyangiitis; Fungal Infection; Infection Parasitic; Inflammation; Malaise; Oropharyngeal Pain; Pneumonia; Pneumonitis; Productive Cough; Secretion Discharge; Sinusitis; Skin Disorder; Sleep Disorder Due To A General Medical Condition; Spirometry Abnormal; Suprapubic Pain; Systemic Inflammatory Response Syndrome; Therapeutic Product Effect Incomplete; Underweight; Vasculitis; Weight Decreased; Wheezing	Salbutamol Sulphate	S		100 Ug, Prn	Glaxosmithkline
	Incruse Ellipta	S		62.5 Ug, Qd	Glaxosmithkline
	Nucala	S	Intravenous (not otherwise specified)	100 Mg, Z, Monthly	Glaxosmithkline
	Ivermectin	S		Unk	Glaxosmithkline
	Prednisone	S	Oral	5 Mg, Unk	Not Reported
	Prednisone	S	Oral	50 Mg, Unk	Not Reported
	Zenhale	S		2 Df, Bid, 200 Ug	Not Reported
	Pantoloc	S		40 Mg, Unk	Not Reported
	Omnaris	S		50 Ug, Unk	Not Reported
	Alvesco	S		200 Ug, Qd	Not Reported
	Plaquenil	S		Unk	Not Reported
	Arava	C		Unk	Not Reported
	Sulfasalazine	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	16676089	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2877461-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported

Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Sulfasalazine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Gold	S	Unknown		Not Reported
	Certolizumab Pegol	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single Use Pre-Filled Syringe	Not Reported
	Ciclosporin	S	Oral		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Pregabalin	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Imuran	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Lyrica	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Piroxicam	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	16718777	EXPEDITED (15-DAY)		DS	CA-ABBVIE-18K-028-2461768-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Nervous System Injury; Stomatitis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Baclofen			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	16743894	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2019-056074			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Pregabalin 100 Mg Capsules, Hard			S	Unknown	1 Dosage Form, 3 Times A Day (1-1-1)		Not Reported
	Pregabalin 100 Mg Capsules, Hard			S	Unknown	100 Milligram, 3 Times A Day (300 Milligram Once A Day)		Not Reported
	Ramipril 2.5mg			S	Oral	1 Dosage Form, Two Times A Day		Aurobindo
	Ramipril 2.5mg			S	Unknown	5 Milligram, Once A Day		Aurobindo
	Sildenafil			S	Unknown	60 Milligram, Once A Day,		Aurobindo

			Daily Dose	
Apixaban	S	Unknown	1 Dosage Form, Two Times A Day (1-0-1)	Not Reported
Apixaban	S	Unknown	2.5 Milligram, Two Times A Day (5 Milligram Once A Day)	Not Reported
Omeprazole	S	Oral	1 Dosage Form, Two Times A Day	Not Reported
Omeprazole	S	Oral	20 Milligram, Two Times A Day	Not Reported
Quensyl	S	Unknown	20 Milligram, Two Times A Day (40 Milligram, Once A Day)	Not Reported
Quensyl	S	Unknown	2 Dosage Form, Once A Day (1 Df, Bid)	Not Reported
Quensyl	S	Unknown	40 Milligram, Two Times A Day (80 Milligram Once A Day)	Not Reported
Roactemra	S	Subcutaneous	162 Milligram, Every Week	Not Reported
Roactemra	S	Subcutaneous	162 Milligram, Every Week	Not Reported
Spasmolyt	S	Unknown	1 Dosage Form, Once A Day (15, Qd ((1-0-0))	Not Reported
Spasmolyt	S	Unknown	30 Milligram, Once A Day	Not Reported
Spasmolyt	S	Unknown	15 Milligram, Once A Day	Not Reported
Tocilizumab	S	Subcutaneous	162 Milligram, Every Week	Not Reported
Volibris	S	Oral	30 Milligram, Once A Day	Not Reported
Volibris	S	Oral	1 Dosage Form, Once A Day	Not Reported
Volibris	S	Unknown	1 Dosage Form, Once A Day	Not Reported
Lyrica	S	Unknown	100 Milligram, 3 Times A Day	Not Reported
Lyrica	S	Unknown	1 Dosage Form, 3 Times A Day (1 Df, 3x/Day (1 - 1-	Not Reported

				1))	
	Ambrisentan	S	Unknown	Unk	Not Reported
	Ambrisentan	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Ambrisentan	S	Unknown	30 Milligram, Once A Day	Not Reported
	Ambrisentan	S	Unknown	30 Milligram, Once A Day	Not Reported
	Eliquis	C	Unknown	5 Milligram, Once A Day (2.5 Mg, Bid)	Not Reported
	Omeprazole	C	Unknown	40 Milligram, Once A Day (20 Milligram, Bid)	Not Reported
	Quensyl	C	Unknown	40 Milligram, Once A Day (20 Mg Bid)	Not Reported
	Ramipril	C	Unknown	5 Milligram, Once A Day (2.5 Mg, Bid)	Not Reported
	Spasmolyt	C	Unknown	15 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	16982974	EXPEDITED (15-DAY)		OT	CA-ROCHE-2448420			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

Fosamax	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17168352	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019228928			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Liver Injury; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Psoriatic Arthropathy; Rheumatoid Arthritis; Swelling; Systemic Lupus	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Mg		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	Unk		Not Reported

Erythematosus; Wound	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Solution	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Fosamax	S	Endocervical	Unk	Not Reported
	Humira	S	Subcutaneous	Solution	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Endocervical	Unk	Not Reported
	Plaquenil	S	Endocervical	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Methotrexate	S	Unknown	Solution	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Endocervical	Unk	Not Reported
	Hydroxychloroquine Phosphate	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution	Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Etanercept	S	Subcutaneous	Unk	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Calcium	C	Unknown	Unk	Glaxosmithkline
	Pantoprazole	C	Unknown	Unk	Glaxosmithkline
	Quetiapine	C	Unknown	Unk	Glaxosmithkline
	Ramipril	C	Unknown	Unk	Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17370427	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533710			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported

Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Prednisone		S	Oral	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Triamcinolone		S	Unknown	Not Reported
	Infliximab		S	Unknown	Not Reported
	Adalimumab		S	Subcutaneous	Not Reported
	Anakinra		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17583547	EXPEDITED (15-DAY)		OT	CA-ROCHE-2571158			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Joint Swelling; Musculoskeletal Stiffness; Presyncope	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Folic Acid			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17605641	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200333272		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Swelling; Laboratory Test Abnormal; Musculoskeletal Disorder; Musculoskeletal Stiffness; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Cimzia Single-Use Prefilled Syringe		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Asacol			S	Unknown			Not Reported
	Azathioprine			S	Oral			Not Reported
	Budesonide			S				Not Reported
	Entyvio			S	Intravenous (not otherwise specified)			Not Reported
	Vedolizumab			S				Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Enbrel	C	Subcutaneous	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported
	Diclofenac	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Tocilizumab	C	Endocervical	Not Reported
	Valsartan	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Wellbutrin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17605713	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332775		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Ankle Fracture; Contraindicated Product Administered; Decreased Appetite; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Swelling; Malaise; Nausea; Off Label Use; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Unevaluable Event; Vomiting	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral	For 3 Years		Not Reported
	Cimzia			S	Subcutaneous	Single Use		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	11 Years		Not Reported

Orencia	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Oral	4 Years	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Xeljanz	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Apo-Azathioprine	S	Unknown		Not Reported
Gold	C	Unknown		Not Reported
Plaquenil /00072602/	C	Unknown		Not Reported
Acetaminophen	C	Unknown		Not Reported
Codeine Phosphate	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Pregabalin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17678265	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004002747			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Atrial Fibrillation; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Off Label Use	Hydroxychloroquine			S	Unknown	400 Mg, Bid, Tablet, (For One Day Followed By 200mg Twice Daily For Four Days)		Concordia
	Hydroxychloroquine			S	Unknown	200 Mg, Bid, Tablet		Concordia
	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Qd		Not Reported
	Azithromycin			S				Not Reported
	Apixaban			C		5 Mg, Bid		Not Reported

	Metoprolol Succinate	C	25 Mg, Qd	Not Reported
	Flecainide	C	50 Mg, Bid	Not Reported
	Flecainide	C	100 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17714374	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200428608			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased; Off Label Use	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17721927	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202004003827			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Acute Respiratory Failure; Off Label Use; Septic Shock	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Oral	400 Mg, Qd, Film Coated Tablet		Concordia
	Enoxaparin	C		Unk		Not Reported
	Cefotaxime	C		Unk		Not Reported
	Spiramycin	C		Unk		Not Reported
	Paracetamol	C		Unk		Not Reported
	Noradrenaline [Norepinephrine]	C		2.4 Mg/Hour		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17729787	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020171239		53 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use In Unapproved Indication; Propofol Infusion Syndrome	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Dolquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Propofol			S	Intravenous (not otherwise specified)	6.6 Mg/Kg Every Hour		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	4 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17739722	EXPEDITED (15-DAY)		HO, OT	BE-ADVANZ PHARMA-202004004406			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Haemolysis; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400mg 2x/D Day 1 Then 200mg 2x/D Day 2 To Day 5 (Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17743985	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200437137		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cerebrovascular Accident; Contraindicated Product Administered; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Wheelchair User	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Asprin			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17771128	EXPEDITED (15-DAY)		DS, LT	FR-MYLANLABS-2020M1045669		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Azithromycin			S	Oral	250 Milligram, Qd		Not Reported
	Nivaquine /00001003/			S	Oral	200 Milligram, Qd (2-3 Cp Par Jour)		Mylan
	Plaquenil /00072602/			S	Oral	2-3 Cp Par Jour		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17778082	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200505939		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Acetaminophen W/Caffeine			C				Not Reported
	Folic Acid			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown			Not Reported

	Arava	C	Unknown	Not Reported
	Tylenol With Codeine	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17780260	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200505923		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Investigation Abnormal; Joint Swelling; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17796109	EXPEDITED (15-DAY)		DE, OT	BE-ADVANZ PHARMA-202004005128			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Off Label Use; Product Use Issue; Respiratory Failure; Wrong Technique In Product Usage Process	Hydroxychloroquine			S	Oral	2 Dosage Form, Bid Capsule		Concordia
	Hydroxychloroquine			S	Oral	1 Dosage Form, Bid,Capsule		Concordia
	Hydroxychloroquine			S	Oral	2 Dosage Form, Bid, Capsule		Concordia
	Hydroxychloroquine			S	Oral	1 Dosage Form, Bid,Capsule		Concordia
	Hydroxychloroquine			S	Oral	1 Dosage Form, Bid, Capsule		Concordia
	Kevzara			S	Intravenous (not otherwise specified)	400 Mg		Not Reported
	Kevzara			S				Not Reported
	Sarilumab Autoinjector			S	Unknown	Unk		Not Reported
	Sarilumab Autoinjector			S				Not Reported
	Azithromycin			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Cefuroxime			C		Unk		Not Reported
	Sodium Chloride			C		Unk		Not Reported
	Clopidogrel Sandoz			C		Unk		Not Reported
	Inderal			C		Unk		Not Reported
	Perindopril			C		Unk		Not Reported
	Morphine Hydrochloride			C		Unk		Not Reported
	Sodium Chloride			C		Unk, Morphine Hydrochloride Mixed With Sodium Chloride		Not Reported
	Dafalgan Forte			C		Unk		Not Reported
	Dafalgan Forte			C				Not Reported

Dafalgan Forte	C		Not Reported
Paracetamol B Braun	C	Unk	Not Reported
Clexane	C	60/0.6 Mg/Ml	Not Reported
Clexane	C	60/0.6 Mg/Ml	Not Reported
Simvastatine	C	Unk	Not Reported
Pantomed	C	Unk	Not Reported
Basaglar	C	Unk	Not Reported
Novorapid	C	Unk	Not Reported
Haldol	C	2 Mg/Ml	Not Reported
Midazolam B Braun	C	5 Mg/Ml	Not Reported
Sodium Chloride	C	Unk,Midazolam Hydrochloride In Sodium Chloride	Not Reported
Remergon	C	Unk	Not Reported
Tamsulosin	C	Unk	Not Reported
Ciproxin	C		Not Reported
Cymbalta	C		Not Reported
Coversyl	C	Unk	Not Reported
Asaflow	C		Not Reported
Contramal	C		Not Reported
Sildenafil Sandoz	C		Not Reported
Zocor	C	Unk	Not Reported
Mirtazapine	C	Unk	Not Reported
Lantus	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17806683	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200517467			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Remicade			S	Intravenous (not			Janssen

Intolerance; Hepatic Enzyme Increased; Nausea; Off Label Use; Pneumonia; Rheumatoid Arthritis			otherwise specified)		
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Simponi	C	Subcutaneous		Not Reported
	Xeljanz	C	Oral		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Wellbutrin	C	Unknown	Extended-Release	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17812671	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200517502		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Cataract Operation; Drug Ineffective	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Celebrex			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Arava			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17823096	EXPEDITED (15-DAY)		HO, OT	NVSC2020US120186		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Ejection Fraction Decreased; Fatigue; Seizure	Trametinib			S	Oral	30 Mg		Novartis
	Trametinib			S	Oral	27 Mg		Novartis
	Trametinib			S	Oral	39 Mg		Novartis
	Comparator Hydroxychloroquine Sulfate			S	Oral	1000 Mg		Not Reported
	Comparator Hydroxychloroquine Sulfate			S	Oral	8750 Mg		Not Reported
	Comparator Hydroxychloroquine Sulfate			S	Oral	11475 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17824262	NON-EXPEDITED			NVSC2020US141645			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Intolerance; Drug Specific Antibody Present; Gastrointestinal Disorder; Therapeutic Product Effect Decreased; Uterine Leiomyoma	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz Xr			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17835087	EXPEDITED (15-DAY)		CA, HO, OT	CA-JNJFOC-20200528676		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anaemia Of Chronic Disease; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Haemodilution; Headache; Hepatic Cyst; Hepatic Haematoma; Hepatitis B Core Antibody Positive; Interferon Gamma Release Assay Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Musculoskeletal Stiffness; Neutropenia; Pulmonary Fibrosis; Pulmonary Mass; Pyrexia; Renal Cyst;	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Isoniazid			S	Unknown			Not Reported
	Varicella-Zoster Immune Globulin			S	Intramuscular			Not Reported
	Plaquenil			S	Oral			Not Reported

Thalassaemia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17835089	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200528679			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Oral	Extended Release		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17835091	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200528675		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Actemra	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17836584	EXPEDITED (15-DAY)		OT	CA-ROCHE-2604914		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Decreased Appetite; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Swelling; Malaise; Nausea; Off Label Use; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Acetaminophen;Codeine Phosphate	C		Not Reported
	Folic Acid	C		Not Reported
	Prednisone	C	Unknown	Not Reported
	Pregabalin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17837483	EXPEDITED (15-DAY)		DS	CA-JNJFOC-20200526841		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate;	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Stelara			S	Subcutaneous			Janssen
	Ibuprofen			S	Oral			Johnson And Johnson
	Ibuprofen			S	Oral			Johnson And Johnson
	Ibuprofen			S	Oral			Johnson And Johnson
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Ibuprofen			S	Oral			Not Reported
	Apo-Ibuprofen			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Apremilast			S	Unknown			Not Reported
	Apremilast			S	Unknown			Not Reported
	Apremilast			S				Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Enbrel	S		Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Infliximab	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S		Not Reported
	Otezla	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Endocervical	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Benadryl /00000402/	C	Unknown	Not Reported
	Colchicine	C	Oral	Not Reported
	Dexilant	C	Unknown	Not Reported
	Febuxostat	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Gravol	C	Unknown	Not Reported
	Mogadon	C	Oral	Not Reported

	Nitrazepam	C	Unknown	Not Reported
	Oxycodone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Uloric	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17837485	EXPEDITED (15-DAY)		HO	CA-JNJFOC-20200526864		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronic Acid			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

						otherwise specified)				
					Rituximab	S	Intravenous (not otherwise specified)			Not Reported
					Sulfasalazine	S	Unknown			Not Reported
					Ciclosporin	C	Unknown			Not Reported
					Prednisone	C	Unknown			Not Reported
					Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17857481	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043563			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Oral	3.0 Milligram, Qd		Not Reported
	Apo-Prednisone			S	Unknown	50.0 Milligram		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17857513	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609890			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Rheumatoid Arthritis	Rituximab		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		C	Subcutaneous	Not Reported
	Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17857567	EXPEDITED (15-DAY)		OT	CA-ROCHE-2610122			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17857587	EXPEDITED (15-DAY)		HO, OT	RU-ADVANZ PHARMA-202005005933			Unknown	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Iron Deficiency Anaemia; Placental Disorder; Placental Insufficiency; Pre-Eclampsia	Hydroxychloroquine			S	Unknown	Unk, Bid		Concordia
	Clexane			S	Unknown	Unk, Bid		Not Reported
	Prednisone			S	Unknown	Unk, Q3h (8 Times Daily)		Not Reported
	Methylprednisolone			S	Unknown	Unk, Bid		Not Reported
	Nifedipine			S	Unknown	90 Mg, Qd		Not Reported
	Methyldopa			S	Unknown	Unk, Qid (Q6h)		Not Reported
	Omeprazole			S	Unknown	Unk, Bid		Not Reported
	Levothyroxine Sodium			S	Unknown	Unk		Not Reported
	Progesterone			S	Unknown	Unk Unk, Qd (400 Daily)		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17857648	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606148			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Drug Ineffective; Foot Deformity; Hand Deformity; Intentional Product Use Issue; Joint Swelling; Leukopenia; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Orencia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Acetaminophen	C		Not Reported
Prednisone	C		Not Reported
Solu-Medrol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17857655	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-02614		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningitis Cryptococcal	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Fingolimod			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17857674	EXPEDITED (15-DAY)		DE, OT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-051575			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Azithromycin			S	Unknown	Unk		Zydus Pharm
	Hidroxicloroquina [Hydroxychloroquine]			S	Unknown	Unk		Not Reported
	Kaletra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17857770	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202005006066			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Hepatocellular Injury; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Oral	600 Mg, Qd		Concordia
	Sarilumab	S	Intravenous (not otherwise specified)	400 Mg, Qd		Not Reported
	Azithromycin	S	Oral	500 Mg, Qd		Not Reported
	Amlodipine	C		Unk		Not Reported
	Indapamide	C		Unk		Not Reported
	Kcl	C		Unk		Not Reported
	Lovenox [Enoxaparin Sodium]	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17857771	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202005005278			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17857815	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202005005881			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Child-Pugh-Turcotte Score Abnormal; Non-Alcoholic Steatohepatitis	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17857817	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608705			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Dose: 1.0 Dosage Forms		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 7.0		Not Reported

Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress				Months	
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous drip	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17857823	EXPEDITED (15-DAY)		OT	CA-ROCHE-2607038		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Golimumab	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Diclofenac	C	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17857958	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2020-2169			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Musculoskeletal Pain; Nausea; Neck Pain; Pain In Extremity; Rash;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

Therapeutic Product Effect Decreased; Treatment Failure; Weight Decreased	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Endocervical	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17857982	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608812		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Intentional Product Use Issue; Nasopharyngitis; Off Label Use; Therapeutic Product Effect Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported

	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Acetaminophen	C		Not Reported
	Arava	C		Not Reported
	Codeine	C		Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17858005	EXPEDITED (15-DAY)		HO	CA-ROCHE-2608888		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Condition Aggravated; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Off Label Use; Pain;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported

Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Ulcer	Cimzia	S	Subcutaneous	Not Reported
	Codeine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported

Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Parenteral	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Ciclosporin	C	Unknown	Not Reported
Ciclosporin	C	Unknown	Not Reported
Prednisolone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17858021	EXPEDITED (15-DAY)		HO	CA-ROCHE-2606496		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Dermatitis; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Neoplasm Skin; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Incomplete; Ulcer	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17858025	EXPEDITED (15-DAY)		OT	CA-SA-2020SA141648			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; Exposure During Pregnancy; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Live Birth; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Desoximetasone			S	Oral			Sanofi
	Diclofenac Sodium			S		50 Mg		Not Reported
	Prednisone			S				Not Reported
	Arava			S				Sanofi
	Folic Acid			S		5 Mg		Not Reported
	Alendronate Sodium			S				Not Reported
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Methotrexate			S		20 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Plaquenil			S		400 Mg, Qd		Sanofi
	Prednisone			S				Not Reported
	Pseudoephedrine Hydrochloride			S				Sanofi
	Sulfasalazine			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S				Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cimzia			S	Subcutaneous	400 Mg		Not Reported
	Cimzia			S				Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Cortisone Acetate			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17858036	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202005005961			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Pneumonia	Hydroxychloroquine			S	Oral	200 Mg, Bid		Concordia
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qw		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17858040	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202005005930			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Pain; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17858929	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020212017		79 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hypokalaemia; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859022	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1243723		64 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypofibrinogenaemia	Hidroxicloroquina Sulfato (2143su)			S	Oral	200 Mg		Teva

	Azitromicina (7019a)	S	Oral	500 Mg	Not Reported
	Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	1 Gm	Not Reported
	Tocilizumab (8289a)	S	Intravenous (not otherwise specified)	400 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859082	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606894			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Subcutaneous	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859197	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1243302		54 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Dermatitis Bullous; Face Oedema; Localised Oedema; Skin Exfoliation	Darunavir			S	Oral	800 Mg		Teva
	Ritonavir Sandoz			S	Oral	1 Dosage Forms		Not Reported
	Plaquenil			S	Oral	2 Dosage Forms		Not Reported
	Tazocin 4 G/0,5 G Polvere Per Soluzione Per Infusione			S		4 Gram		Not Reported
	Clexane			S	Subcutaneous	1 Dosage Forms		Not Reported
	Depakin Chrono 300 Mg Compresse A Rilascio Prolungato			C				Not Reported
	Insulin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859219	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243540			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Eye Disorder; Hand Deformity; Infection; Lung Disorder; Musculoskeletal Pain; Peripheral Swelling; Pulmonary Hypertension	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859308	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202005005082			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859367	EXPEDITED (15-DAY)		DE, OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-249218		86 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Azithromycin			S	Unknown	Unk		Sun
	Hidroxicloroquina (2143a)			S	Unknown	Unk		Not Reported
	Kaletra			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859384	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187404		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Off Label Use; Treatment	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not	8 Mg/Kg		Not Reported

Failure			otherwise specified)	
	Sulfasalazine	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Subcutaneous	Not Reported
	Apo-Hydroxyquine	S	Oral	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Apo-Leflunomide	S	Subcutaneous	Not Reported
	Cyclosporin	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Neoral	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Arava	C	Oral	Not Reported
	Risedronate	C	Oral	Not Reported
	Risedronate	C	Oral	Not Reported
	Cimzia	C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859385	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609357			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Perforation; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859450	EXPEDITED (15-DAY)		HO, LT, OT	CA-JNJFOC-20200537326		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Ill-Defined Disorder; Infection; Kidney Infection; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Sepsis; Therapeutic Response Decreased	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859463	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202005006112			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Off Label Use; Vasculitis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	600 Mg, Qd, Coated Tablet		Concordia
	Kevzara			S	Subcutaneous	400 Mg, Qd, Concentrate For Solution For Injection/Infusion		Not Reported
	Zithromax			S	Oral	250 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859513	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-2170			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Pneumonia; Pulmonary Mass; Tinnitus	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859514	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-2174			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

	Xeljanz	S	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859528	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-2180		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Herpes Zoster; Hypertension; Pneumonia	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859534	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-2172		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral; Condition Aggravated; Drug Ineffective; Drug Intolerance; Herpes Zoster; Hypertension; Inflammation; Joint Swelling; Musculoskeletal Disorder; Musculoskeletal	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil S			S	Unknown			Not Reported

Stiffness; Pain; Pancreatitis; Peripheral Swelling; Pneumonia; Psoriatic Arthropathy; Scar	Prednisone	C	Unknown	Not Reported
	Enbrel	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859539	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-2184		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Synovitis; X-Ray Abnormal	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Penicillin G			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859544	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-2186			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Actinic Keratosis; Arthrodesis; Asthma; Coordination Abnormal; Dry Eye; Gastrointestinal Disorder; Nausea; Palpitations; Photosensitivity Reaction; Rash; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Depo-Medrol			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859563	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243624		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cartilage Atrophy; Drug Ineffective; Drug Ineffective; Joint Swelling; Nausea; Nephrotic Syndrome; Periorbital Oedema; Renal Disorder; Skin Erosion; Therapeutic Product Effect Decreased;	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported

Therapeutic Product Effect Decreased; Wrist Deformity	Leflunomide		C	Oral	10 Milligram Daily;	Not Reported
	Naproxen		C	Unknown		Not Reported
	Sulfasalazine		C		3 Gram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859574	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1243850			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Akathisia; Anxiety; Anxiety; Nightmare	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859578	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243571			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Infection; Joint Swelling; Liver Function Test Increased; Pain; Paralysis; Skin Infection; Treatment Failure; Urinary Tract Infection	Methotrexate			S	Unknown			Barr
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Diphenhydramine			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859880	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043838			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphthous Ulcer; Drug Ineffective; Mouth Ulceration; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859921	EXPEDITED (15-DAY)		HO	CA-ROCHE-2609229		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Prednisone	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859933	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202005005085			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported
	Zinc			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859973	EXPEDITED (15-DAY)		LT	NVSC2020FR155031		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Ventricular Tachycardia	Azithromycin			S	Oral	250 Mg, Qd		Novartis
	Lasilix			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Sufentanil			C	Intravenous (not otherwise specified)			Not Reported
	Perfalgan			C	Intravenous (not otherwise specified)			Not Reported

	Noradrenaline	C	Intravenous (not otherwise specified)	Not Reported
	Midazolam	C	Intravenous (not otherwise specified)	Not Reported
	Tazocilline	C	Intravenous (not otherwise specified)	Not Reported
	Transipeg	C	Oral	Not Reported
	Potassium	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860288	EXPEDITED (15-DAY)		DS	FR-VALIDUS PHARMACEUTICALS LLC-FR-2016VAL001307			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Peripheral Sensorimotor Neuropathy	Furosemide			S	Oral	Unk		Validus
	Plaquenil /00072603/			S	Oral	Unk		Not Reported
	Atorvastatin Calcium			S	Oral	Unk		Not Reported
	Esomeprazole			S	Oral	Unk		Not Reported
	Duloxetine Hydrochloride			S	Oral	Unk		Not Reported
	Morphine Sulfate			S	Oral	Unk		Not Reported
	Cortancyl			S	Oral	Unk		Not Reported
	Alendronate Sodium			S	Oral	Unk		Not Reported
	Forlax			S	Oral	Unk		Not Reported
	Dutasteride			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Clonazepam			S	Oral	Unk		Not Reported
	Cacit Vitamine D3			S	Oral	Unk		Not Reported
	Salazopyrin			S	Oral	Unk		Not Reported
	Lexomil			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860327	EXPEDITED (15-DAY)		HO	FR-ADVANZ PHARMA-202005006128			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Decreased Appetite; General Physical Health Deterioration; Loss Of Personal Independence In Daily Activities	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Kevzara			S	Intravenous (not otherwise specified)	400 Mg, Qd (Single Dose)		Not Reported
	Ramipril			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Amlor			C		Unk		Not Reported
	Gutron			C		Unk		Not Reported
	Imeth			C		Unk		Not Reported
	Allopurinol			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Lovenox			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860394	EXPEDITED (15-DAY)		OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2020VAL000448			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Hepatocellular Injury; Off Label Use	Cefotaxime Sodium			S	Intravenous (not otherwise specified)	Unk		Validus
	Plaquenil /00072603/			S	Oral	400 Mg, Qd		Not Reported
	Plaquenil /00072603/			S				Not Reported
	Pantoprazole Sodium			S	Oral	20 Mg, Qd		Not Reported
	Azithromycin			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860458	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1054257		86 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Azithromycin			S	Unknown	500 Milligram, On Day 1		Not Reported
	Azithromycin			S	Unknown	250 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Three Times A Day		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860556	EXPEDITED (15-DAY)		DE, OT	ES-PFIZER INC-2020215876		86 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Depressed Mood; Hypertransaminasaemia; Long Qt Syndrome; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S		Unk, Every 48 Hours		Pfizer
	Methylprednisolone Sodium Succinate			S		Unk		Pfizer
	Kaletra			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860780	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608972			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Headache; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Nausea; Neck Pain; Off Label Use; Overlap Syndrome; Pain In Extremity; Pain In Jaw;	Rituximab			S	Intravenous drip			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine Sodium			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Proteinuria; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Treatment Failure; Vasculitis; Weight Decreased	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Penicillamine	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Amitriptyline Hydrochloride	C		Not Reported
	Doxycycline	C		Not Reported
	Sulfasalazine	C		Not Reported
	Tobramycin	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860864	EXPEDITED (15-DAY)		DE, HO	GR-MYLANLABS-2020M1053729		51 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Shock	Azithromycin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Anakinra			S	Intravenous (not otherwise specified)	200 Milligram, Q8h		Mylan
	Teicoplanin			S	Unknown	Unk		Mylan
	Meropenem			S	Unknown	Unk		Mylan
	Hydrocortisone			C	Intravenous (not otherwise specified)	300 Milligram, Qh		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860882	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243461		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Blood Creatinine Increased; Diarrhoea; Drug Ineffective;	Methotrexate			S	Unknown			Barr
	Arava			S	Oral	10 Milligram Daily;		Not Reported

Glomerular Filtration Rate Decreased; Haemoglobin Decreased; Lymphocyte Count Decreased; Mean Cell Volume Decreased; Red Cell Distribution Width Increased	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860884	EXPEDITED (15-DAY)		DE, HO, OT	GR-MYLANLABS-2020M1053730		74 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatomegaly; Hypoxia; Inflammatory Marker Increased; Off Label Use; Pyrexia; Shock; Splenomegaly	Azithromycin			S		Unk		Not Reported
	Anakinra			S	Intravenous (not otherwise specified)			Mylan
	Teicoplanin			S		Unk		Mylan
	Hydroxychloroquine			S		Unk		Mylan
	Meropenem			S		Unk		Mylan
	Hydrocortisone			C	Intravenous (not otherwise specified)	300 Milligram, Qh		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860890	EXPEDITED (15-DAY)		HO, OT	ES-BIOVITRUM-2020ES2835		77 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Anakinra			S	Intravenous drip			Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Lopinavir			S	Oral			Not Reported
	Ritonavir			S	Oral			Not Reported

	Enoxaparin	S	Subcutaneous		Not Reported
	Acetyl Salicylic Acid	C	Oral		Not Reported
	Omeprazole	C	Oral		Not Reported
	Atorvastatin	C	Oral		Not Reported
	Furosemide	C	Intravenous (not otherwise specified)		Not Reported
	Amlodipine	C	Oral		Not Reported
	Valsartan	C	Oral		Not Reported
	Hydrochlorothiazide	C	Oral	Dose. 12.5 Mg	Not Reported
	Pentoxifylline	C	Oral		Not Reported
	Atorvastatin	C	Oral		Not Reported
	Carvedilol	C	Oral		Not Reported
	Acetylcysteine	C	Intravenous (not otherwise specified)		Not Reported
	Clopidogrel	C	Oral		Not Reported
	Iron	C	Intravenous (not otherwise specified)		Not Reported
	Piperacillin/Tazobactam	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860891	EXPEDITED (15-DAY)		DE, OT	GR-MYLANLABS-2020M1053731		84 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anuria; Off Label Use; Shock; Splenomegaly	Azithromycin			S		Unk		Not Reported
	Anakinra			S	Intravenous (not otherwise specified)	200 Milligram, Q8h		Mylan
	Teicoplanin			S		Unk		Mylan
	Meropenem			S		Unk		Mylan
	Hydroxychloroquine			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860902	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243082		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Disorder; Drug Ineffective; Head Injury; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Subcutaneous			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860903	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243128		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown	500 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860985	EXPEDITED (15-DAY)		DE	ES-MYLANLABS-2020M1054146		73 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Coma; Hypotension; Tachycardia	Glyceryl Trinitrate			S	Topical	5 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Mylan
	Digoxin			S	Intravenous (not otherwise specified)	Unk, Every		Mylan
	Metamizole			S	Intravenous (not otherwise specified)	1 Gram Every 8 Hour		Mylan
	Paracetamol			C	Intravenous (not otherwise specified)	1 Gram Every 8 Hour		Mylan
	Pantoprazole			C	Oral	40 Milligram, Qd		Mylan
	Methylprednisolone			C	Intravenous (not otherwise specified)	40 Milligram, Qd		Mylan
	Piperacilina + Tazobactam			C	Intravenous (not otherwise specified)	4 Gram Every 8 Hour		Mylan
	Amoxicillin Clavulanic Acid			C	Intravenous (not otherwise specified)	2 Gram Every 8 Hour		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861051	EXPEDITED (15-DAY)		OT	CA-SA-2020SA142138			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus;	Desoximetasone			S	Oral			Sanofi
	Arava			S	Oral			Sanofi
	Methotrexate			S	Oral	25 Mg		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Hydroxychloroquine			S	Oral	25 Unk		Sanofi
	Plaquenil			S	Oral			Sanofi

Swelling; Systemic Lupus Erythematosus	Folic Acid	S		500 Mg	Not Reported
	Diclofenac	S	Unknown		Not Reported
	Apo-Prednisone	S		5 Mg	Not Reported
	Actemra	S			Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone Acetate	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Fosamax	S			Not Reported
	Humira	S		40 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861052	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA142051			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme	Topicort			S	Cutaneous			Sanofi
	Diclofenac Sodium			S				Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Arava			S	Oral			Sanofi
	Cetirizine Hydrochloride			S		10 Mg		Not Reported
	Desoximetasone			S	Oral			Sanofi
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S		10 Mg		Not Reported
	Folic Acid			S		1 Mg		Not Reported

Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Hydroxychloroquine	S	Oral	400 Mg, Qd	Sanofi
	Leflunomide	S	Oral		Sanofi
	Methotrexate	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate	S	Oral	25 Unk	Not Reported
	Plaquenil	S	Oral	400 Mg, Qd	Sanofi
	Prednisone	S	Oral		Not Reported
	Pseudoephedrine Hydrochloride	S			Sanofi
	Sulfasalazine	S	Oral	1000 Mg, Bid	Not Reported
	Sulfasalazine	S	Oral	500 Mg	Not Reported
	Cortisone Acetate	S	Topical	25 Mg	Not Reported
	Tofacitinib Citrate	S		5 Mg, Bid	Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous	Unk Mg	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Oral	1000 Mg, Bid	Not Reported
	Phthalylsulfathiazole	S	Oral	500 Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Tofacitinib	S		5 Mg, Bid	Not Reported
	Salazopyrin	C			Not Reported
	Atasol [Paracetamol]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861056	EXPEDITED (15-DAY)		OT	CA-SA-2020SA142108			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Desoximetasone	S	Oral		Sanofi
	Cortisone Acetate	S	Topical	25 Mg	Not Reported
	Diclofenac Sodium	S			Not Reported
	Prednisone	S			Not Reported
	Arava	S			Sanofi
	Cetirizine Hydrochloride	S			Not Reported
	Folic Acid	S		1 Mg	Not Reported
	Folic Acid	S		5 Mg	Not Reported
	Alendronate Sodium	S	Oral		Not Reported
	Hydroxychloroquine	S			Sanofi
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Intra-arterial	25 Mg	Not Reported
	Sulfasalazine	S		500 Mg	Not Reported
	Pseudoephedrine Hydrochloride	S			Sanofi
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Hydroxychloroquine Phosphate	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861134	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606920			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Tofacitinib Citrate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861182	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2020212030		77 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Off Label Use; Product Use In Unapproved Indication; Purpura Senile; Rash; Rash Erythematous; Rash Pruritic; Senile Pruritus	Azithromycin			S	Oral	1 Df, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861353	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243470			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Intramuscular	12.5 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Intramuscular			Barr
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Arava			S	Unknown	4.2857 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861385	EXPEDITED (15-DAY)		HO, OT	FR-TEVA-2020-FR-1241998		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete; Bundle Branch Block; Conduction Disorder; Decreased Appetite; Drug Ineffective; Dysphagia; Dysphonia; Left Ventricular Hypertrophy; Muscle Injury; Myopathy Toxic; Subacute Cutaneous Lupus Erythematosus; Weight Decreased	Fenofibrate			S	Unknown			Actavis
	Hydroxychloroquine			S	Unknown	400mg Per Day 7.4 Mg/Kg/Day		Not Reported
	Chloroquine			S	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Clopidogrel			C	Unknown			Not Reported
	Ranitidine			C	Unknown			Not Reported
	Clobetasol			C	Unknown	1 Application/Day		Not Reported
	Tramadol/Paracetamol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861386	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243681			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Zostavax	S	Subcutaneous		Not Reported
	Zostavax	S	Intravenous (not otherwise specified)		Not Reported
	Cortisone Acetate	C	Subcutaneous		Not Reported
	Desoximetasone	C	Subcutaneous		Not Reported
	Diclofenac	C	Subcutaneous		Not Reported
	Xeljanz	C	Oral	20 Milligram Daily;	Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861398	EXPEDITED (15-DAY)		OT	CA-SA-2020SA142306			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Wound	Desoximetasone			S				Sanofi
	Cortisone Acetate			S		25 Mg		Not Reported
	Hydroxychloroquine Sulfate			S				Sanofi
	Prednisone			S				Not Reported
	Arava			S				Sanofi
	Cetirizine Hydrochloride			S				Not Reported
	Folic Acid			S	Oral	25 Mg		Not Reported
	Folic Acid			S		5 Mg		Not Reported
	Alendronate Sodium			S				Not Reported
	Leflunomide			S				Sanofi
	Methotrexate			S	Oral	25 Mg		Not Reported
	Plaquenil			S		400 Mg, Qd		Sanofi
	Sarilumab			S				Sanofi
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Pseudoephedrine Hydrochloride			S				Sanofi
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Pseudoephedrine			S				Not Reported
	Cimzia			S				Not Reported
	Enbrel			S				Not Reported

	Humira	S	Subcutaneous	4 Mg	Not Reported
	Orencia	S			Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Reactine [Cetirizine Hydrochloride]	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S			Not Reported
	Simponi	S			Not Reported
	Stelara	S			Not Reported
	Topicort [Desoximetasone]	S			Not Reported
	Xeljanz	S		5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861413	EXPEDITED (15-DAY)		HO, OT	IT-SA-2020SA138478		54 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Dermatitis Bullous; Face Oedema; Localised Oedema; Off Label Use; Skin Exfoliation	Plaquenil			S	Oral			Sanofi
	Plaquenil			S				Sanofi
	Darunavir			S	Oral			Not Reported
	Piperacillin Sodium/Tazobactam Sodium			S				Not Reported
	Clexane			S	Subcutaneous			Sanofi
	Depakin Chrono [Valproate Sodium]			C				Not Reported
	Ritonavir Sandoz			S	Oral			Not Reported
	Insulin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861427	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243455			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Impaired	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Work Ability; Joint Stiffness; Mobility Decreased; Muscular Weakness; Musculoskeletal Stiffness; Nausea; Ototoxicity; Pain In Extremity; Spinal Pain; Vomiting	Humira	S	Subcutaneous	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861457	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243238			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Intramuscular			Barr
	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861495	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243102		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861610	EXPEDITED (15-DAY)		LT, OT	CA-TEVA-2020-CA-1243669		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disease Progression; Dysphonia; Dyspnoea; Odynophagia; Product Use In Unapproved Indication; Rheumatoid Arthritis; Stridor	Methotrexate			S	Unknown			Barr
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861615	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243825			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown	12.5 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Intramuscular			Barr
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861655	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2605562			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Pain; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown	Therapy Duration: 9.0 Months		Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Therapy Duration: 9.0 Months		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 4.0 Years		Not Reported

Enbrel	S	Unknown		Not Reported
Gold	S	Unknown		Not Reported
Humira	S	Unknown		Not Reported
Humira	S	Subcutaneous	Therapy Duration: 4.0 Years	Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulphate	S	Unknown		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Lyrica	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Pregabalin	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 2.0 Years	Not Reported
Simponi	S	Subcutaneous		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous		Not Reported
Folic Acid	C	Unknown		Not Reported
Leflunomide	C	Unknown		Not Reported
Piroxicam	C	Unknown		Not Reported
Prednisone	C	Oral		Not Reported

	Tofacitinib Citrate	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861700	EXPEDITED (15-DAY)		HO	IT-JNJFOC-20200533665		54 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Dermatitis Bullous; Face Oedema; Localised Oedema; Off Label Use; Product Use In Unapproved Indication; Skin Exfoliation	Darunavir			S	Oral			Janssen
	Plaquenil /00072602/			S	Oral			Not Reported
	Tazocin			S	Unknown			Not Reported
	Ritonavir			S	Oral			Not Reported
	Clexane			S	Subcutaneous			Not Reported
	Depakin Chrono /00228502/			C				Not Reported
	Insulin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861817	EXPEDITED (15-DAY)		OT	NVSC2020FR155119		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Azithromycin			S	Other	Cf Commentaires		Novartis
	Plaquenil			S	Other	Cf Commentaires		Not Reported
	Primperan			S	Intravenous drip	30 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861865	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043659			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported

Decreased	Cimzia	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Methotrexate	S	Unknown	20 Milligram	Not Reported
	Sulfasalazine	S	Unknown	1 Gram, Bid	Not Reported
	Xeljanz	C	Unknown	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861915	EXPEDITED (15-DAY)		OT	CA-ROCHE-2607904			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Celecoxib			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861921	EXPEDITED (15-DAY)		OT	NVSC2020FR153002		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Abnormal; Breast Cancer Metastatic; Burning Sensation; Constipation; Dementia Alzheimer'S Type; Expired Product Administered; Gait Disturbance; Intentional Product Misuse; Malaise; Off Label Use; Paronychia; Skin	Amoxicillin Trihydrate + Potassium Clavulanate			S	Unknown	Unk		Novartis
	Amoxicillin Trihydrate + Potassium Clavulanate			S				Novartis
	Amoxicillin Trihydrate + Potassium Clavulanate			S				Novartis
	Plaquenil			S	Unknown	2 Df, Q12h (Bid,One In Morning And One In Evening)		Not Reported

Plaque; Systemic Lupus Erythematosus; Toe Amputation	Plaquenil		S	Unknown	3 Df	Not Reported
	Plaquenil		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17862406	NON-EXPEDITED			NVSC2020US156293			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17862412	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043984			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	2 Every 1 Days		Not Reported
	Methotrexate			S	Unknown	1 Every 1 Weeks		Not Reported
	Sulfasalazine			C	Unknown	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17863104	EXPEDITED (15-DAY)		OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2020VAL000469			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Thrombocytopenia	Furosemide			S	Unknown	Unk		Validus
	Sarilumab			S	Subcutaneous	400 Mg, 1x		Not Reported
	Azithromycin			S	Oral	250 Mg, Unk		Not Reported

Plaquenil /00072603/	S	Oral	600 Mg, Unk	Not Reported
Bisoprolol	S	Unknown	Unk	Not Reported
Amiodarone Hydrochloride	S	Unknown	Unk	Not Reported
Enoxaparin Sodium	S	Unknown	Unk	Not Reported
Paroxetine Hydrochloride	S	Unknown	Unk	Not Reported
Atorvastatin	S	Unknown	Unk	Not Reported
Levothyroxine	C		Unk	Not Reported
Alprazolam	C		Unk	Not Reported
Racecadotril	C		Unk	Not Reported
Kcl	C		Unk	Not Reported
Lansoprazole	C		Unk	Not Reported
Clopidogrel	C		Unk	Not Reported
Tamsulosin	C		Unk	Not Reported
Eplerenone	C		Unk	Not Reported
Amlor	C		Unk	Not Reported
Gabapentin	C		Unk	Not Reported
Seresta	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17863471	EXPEDITED (15-DAY)		OT	NVSC2020CA153559			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; General Physical Health Deterioration; Ill-Defined Disorder; Inflammation; Mobility Decreased; Musculoskeletal Stiffness; Pain; Pulmonary Toxicity; Therapeutic Response Decreased	Erelzi			S	Subcutaneous	50 Mg, Qw		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	5 Df		Not Reported
	Cortisone			C	Unknown	Unk		Not Reported
	Tylenol			C	Unknown	Unk		Not Reported

	Ibuprofen		C	Unknown	Unk	Not Reported
	Plaquenil		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17863576	EXPEDITED (15-DAY)		DS	CA-ROCHE-2609041		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Increased; Drug Ineffective; General Physical Health Deterioration; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Osteoarthritis; Pain; Physical Disability; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Increased; White Blood Cell Count Increased	Rituximab			S	Intravenous (not otherwise specified)	1.0 Months		Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	5.0 Years		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Infliximab			S	Unknown	2.0 Months		Not Reported
	Humira			S	Subcutaneous	4.0 Years		Not Reported
	Etanercept			S	Subcutaneous	610.0 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17863631	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-2021813US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Hyperkalaemia	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Plaquenil			S	Oral	600 Mg, Qd		Not Reported
	Zithromax			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17864449	DIRECT	Y	LT			70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Liver Function Test Increased; Pneumonia	Lacosamide			S	Oral			Not Reported
	Atorvastatin			C				Not Reported
	Clobazam			C				Not Reported
	Lacosamide			C				Not Reported
	Vancomycin			C				Not Reported
	Doxycycline			C				Not Reported
	Aztreonam			C				Not Reported
	Tigecycline			C				Not Reported
	Hydroxychloroquine 200mg			S				Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	13932857	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP017314		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity;	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Alendronate			S	Unknown	70 Mg, Q.Wk.		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Cyclosporine			S	Unknown	150 Mg, Qd		Apotex
	Methotrexate			S	Unknown	12 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	12.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	12.5 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	10 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	10 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	12 Mg, Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, Q.O.Wk.		Not Reported

Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Enbrel	S	Unknown	25 Mg, Unk	Not Reported
	Enbrel	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
	Enbrel	S	Subcutaneous	25 Mg, Q.O.Wk.	Not Reported
	Humira	S	Unknown	40 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Mg, Q.Wk.	Not Reported
	Orencia	S	Unknown	Unk, 275 (Unspecified Unit)	Not Reported
	Orencia	S	Unknown	780 Mg, Q.Wk.	Not Reported
	Rituxan	S	Unknown	1000 Mg, Bid	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S			Not Reported
	Tocilizumab	S	Unknown	680 Mg, 1 Every 4 Weeks	Not Reported
	Tocilizumab	S	Unknown	360 Mg, Q.M.T.	Not Reported
	Tocilizumab	S	Unknown	680 Mg, Q.M.T.	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk, 365 (Unspecified Unit)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	360 Mg, Q.M.T.	Not Reported
	Actemra	S	Unknown	680 Mg, Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	680 Mg, 1 Every 4 Week	Not Reported

Actemra	S	Unknown	360 Mg, Q.Wk.		Not Reported
Myochrysine	S	Unknown	50 Mg, Q.M.T.		Not Reported
Myochrysine	S	Intramuscular	50 Mg, Q.M.T.		Not Reported
Rituximab	S	Intravenous drip	1000 Mg, Bid		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Bid		Not Reported
Fosamax	S	Unknown	70 Mg, Q.Wk.		Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Ciclosporin	C	Unknown	150 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	13946397	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017455		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Azathioprine			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, B.I.Wk.		Not Reported

	Etanercept	S	Subcutaneous	25 Mg, B.I.Wk.	Not Reported
	Gold	S	Intramuscular	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Kineret	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	14682648	EXPEDITED (15-DAY)		HO	CA-ROCHE-2089239		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Infection; Rash; Urticaria	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous	2 Years		Not Reported
	Certolizumab Pegol			S	Subcutaneous	15 Days		Not Reported
	Certolizumab Pegol			S	Subcutaneous	1 Days		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral	2 Months		Not Reported
	Methotrexate Sodium			S	Subcutaneous	2 Months		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	2 Months		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			C				Not Reported

Methotrexate	C				Not Reported
Prednisone	C				Not Reported
Tofacitinib Citrate	C				Not Reported
Viread	C	Unknown			Not Reported
Naproxen	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	15509701	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016273080		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Dysphagia; Gastrooesophageal Reflux Disease; Glaucoma; Pharyngeal Swelling	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Plaquenil			S		200 Mg, 2x/Day		Not Reported
	Plaquenil			S		200 Mg, 1x/Day		Not Reported
	Plaquenil			S		200 Mg, 2x/Day		Not Reported
	Atorvastatin			C		20 Mg, Unk		Not Reported
	Latanoprost			C		Unk, ([125mg/2.5ml])		Not Reported
	Stiolto Respimat			C		Unk		Not Reported
	Claritin [Loratadine]			C		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	15620857	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556897-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Knee Arthroplasty; Mouth	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported

Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Apo-Leflunomide	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	15713218	EXPEDITED (15-DAY)		HO, OT	US-GLENMARK PHARMACEUTICALS-2018GMK038625		1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Heart Rate Deceleration Abnormality; Lymphopenia	Tacrolimus			S	Transplacental	Unk		Glenmark
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Azathioprine			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported
	Betamethasone			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	15801139	EXPEDITED (15-DAY)		HO	CA-ABBVIE-19K-028-2617050-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Joint Laxity; Limb Deformity; Loose Body In Joint; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Aleve			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Folic Acid			C	Subcutaneous			Not Reported
	Methotrexate			C				Not Reported
	Plaquenil			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	15899841	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2019048311		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Immunodeficiency; Nasal	Flector			S	Transdermal	1 Patch To Skin, Twice A Day		Pfizer

Congestion; Pain; Suspected Covid-19	Flector	S				Pfizer
	Diclofenac Sodium	S	Oral	Unk		Not Reported
	Oxymorphone	S		Unk		Not Reported
	Oxycodone	S		Unk		Not Reported
	Hydrocodone	S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Unk		Not Reported
	Pennsaid	S		Unk		Not Reported
	Voltaren [Diclofenac Sodium]	S		Unk		Not Reported
	Cbd	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	15974800	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013007			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Abatacept			S	Subcutaneous	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Alendronate Sodium	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	16286005	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-044948		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anticipatory Anxiety; Arthralgia; Asthenia; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Apo-Prednisone			S	Unknown	9 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Every 1 Day		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Enbrel			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Plaquenil S			S	Unknown	200 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	9 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

			otherwise specified)		
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Xeljanz	S	Oral	5.0 Milligram, Qd	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Etanercept	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Dexamethasone	C	Unknown	Unk	Not Reported
	Gabapentin	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Cortisone	C	Unknown	Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	16462022	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006323			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral	Apo-Acetaminophen			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Oral	200 Mg, Unk		Apotex
	Acetaminophen			S	Unknown	325 Mg, Unk		Apotex
	Apo-Prednisone			S	Unknown	20 Ng, Unk		Apotex
	Leflunomide			S	Unknown	200 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Acetaminophen			S	Unknown	Unk		Not Reported

Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	W/Diphenhydramine Hydrochloride				
	Actemra	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Arava	S	Oral	20 Mg, Qd	Not Reported
	Arava	S	Oral	20 Mg, Qd	Not Reported
	Arava	S	Unknown	10 Mg, Qd	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	50 Mg, Q.Wk.	Not Reported
	Enbrel	S	Unknown	50 Mg, Unk (4 Every 1 Week)	Not Reported
	Enbrel	S	Unknown	40 Mg, Unk (4 Every 1 Week)	Not Reported
	Enbrel	S	Unknown	50 Mg, Qd	Not Reported
	Enbrel	S	Unknown	40 Mg, Q.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Orencia	S	Unknown	200 Mg, Unk	Not Reported
	Orencia	S	Unknown	750 Mg, Unk	Not Reported
	Plaquenil /00072602/	S	Oral	200 Mg, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	5 Mg, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Tylenol /00020001/	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2000 Mg, Unk	Not Reported

Sulfasalazine	S	Oral	2000 Mg, Unk		Not Reported
Sulfasalazine	S	Oral	1000 Mg, Bid		Not Reported
Sulfasalazine	S	Oral	500 Mg, Bid		Not Reported
Sulfasalazine	S	Oral	2000 Mg, Unk		Not Reported
Synthroid	C	Unknown	Unk		Not Reported
Synthroid	C				Not Reported
Acetaminophen/Codein Phosphate	C	Unknown	Unk		Not Reported
Meloxicam	C	Unknown	Unk		Not Reported
Methotrexate	C	Unknown	25 Df, Q.Wk.		Not Reported
Methotrexate	C	Unknown	Unk Unk, Q.Wk.		Not Reported
Methotrexate	C	Subcutaneous	Unk, 4 Every 1 Week		Not Reported
Methotrexate	C	Unknown	20 Mg, Q.Wk.		Not Reported
Methotrexate	C	Subcutaneous	25 Mg, Q.Wk.		Not Reported
Tylenol With Codeine No.3	C	Unknown	Unk		Not Reported
Leflunomide	C	Unknown	20 Mg, Qd		Not Reported
Hydromorphone Hcl	C	Unknown	Unk		Not Reported
Celebrex	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Tylenol With Codein #3	C	Unknown	Unk		Not Reported
Celecoxib	C	Unknown	Unk		Not Reported
Codeine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	16613478	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20190721988		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen

Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Disorder; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Product Effect Decreased; Therapeutic	Stelara	S	Subcutaneous	Janssen
	Motrin	S	Oral	Johnson And Johnson
	Motrin	S	Oral	Johnson And Johnson
	Alendronate Sodium	S	Unknown	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Apo-Ibuprofen	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Apremilast	S	Unknown	Not Reported
	Apremilast	S		Not Reported
	Apremilast	S		Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Sulfasalazine	S	Endocervical	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Otezla	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported

Product Effect Incomplete; Tongue Disorder; Ulcer	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Infliximab	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Codeine	S	Unknown	Not Reported

Cimzia	S	Subcutaneous	Not Reported
Alendronic Acid	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Ciclosporin	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Colchicine	C	Oral	Not Reported
Febuxostat	C	Unknown	Not Reported
Gravol	C	Unknown	Not Reported
Mogadon	C	Oral	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Uloric	C	Oral	Not Reported
Xeljanz	C	Unknown	Not Reported
Oxycodone	C	Unknown	Not Reported
Nitrazepam	C	Oral	Not Reported
Folic Acid	C	Unknown	Not Reported
Dexilant	C	Oral	Not Reported
Prednisolone	C	Unknown	Not Reported
Prednisolone	C	Unknown	Not Reported
Benadryl	C	Unknown	Not Reported
Ciclosporin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	16714551	EXPEDITED (15-DAY)		OT	PHHY2019DE188505			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Ramipril			S	Oral	1 Df, Qd (1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval		Not Reported
	Omeprazole			S	Oral	1 Df, Qd (1 Df, 2x/Day (1 - 0 - 1))		Novartis
	Omeprazole			S	Unknown	20 Mg, Bid		Novartis
	Pregabalin			S	Unknown	3 Df, Qd		Not Reported
	Apixaban			S	Unknown	2 Df (1 Dosage Form, Bid (1-0-1))		Not Reported
	Apixaban			S	Unknown	5 Mg, Qd (2.5 Milligram, Bid)		Not Reported
	Apixaban			S	Unknown	2.5 Mg, Bid		Not Reported
	Sildenafil Citrate			S	Unknown	60 Mg, Qd		Not Reported
	Ambrisentan			S	Unknown	30 Mg, Qd (Film Coated Tablet)		Not Reported
	Ambrisentan			S	Unknown	1 Df, Qd		Not Reported
	Quensyl			S	Unknown	2 Df, Qd (1 Df, Bid (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval)		Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval		Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval		Not Reported

Quensyl	S	Unknown	20 Mg Bid	Not Reported
Spasmolyt	S	Unknown	30 Mg, Qd (Number Of Separate Dosages: 1 Number Of Units In The Interval: 1 Definition Of The Interv	Not Reported
Spasmolyt	S	Unknown	1 Df, Qd	Not Reported
Spasmolyt	S	Unknown	1 Df, Qd; 1 Number Of Units In The Interval: 1 Definition Of The Interval: Day	Not Reported
Eliquis	S	Unknown	2 Df, Qd	Not Reported
Eliquis	S	Unknown	2.5 Mg Bid	Not Reported
Roactemra	S	Subcutaneous	162 Milligram, Qwk	Not Reported
Roactemra	S	Subcutaneous	162 Milligram, Qwk	Not Reported
Roactemra	S	Unknown	162 Mg, Qw	Not Reported
Volibris	S	Oral	30 Mg, Qd	Not Reported
Volibris	S	Oral	1 Df, Qd	Not Reported
Volibris	S	Oral	1 Dosage Form, Qd	Not Reported
Volibris	S	Oral	1 Dosage Form, Qd	Not Reported
Lyrica	S	Unknown	300 Mg, Qd (100 Milligram, Tid)	Not Reported
Lyrica	S	Unknown	100 Milligram, Tid	Not Reported
Lyrica	S	Unknown	100 Milligram, Tid	Not Reported
Lyrica	S	Unknown	100 Mg, Tid	Not Reported
Tocilizumab	S	Subcutaneous	162 Mg, Qw	Not Reported
Tocilizumab	S	Subcutaneous	162 Mg, Qw	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	16778722	EXPEDITED (15-DAY)		DS, HO, OT	CA-ADVANZ PHARMA-GSH201706-003601			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Pruritus; Rash; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Ulcer	Hydroxychloroquine	S	Oral	200 Mg, Qd	Concordia
	Leflunomide	S	Oral	20 Mg, Unk	Not Reported
	Leflunomide	S	Oral	20 Mg, Unk	Not Reported
	Actemra	S	Unknown	680 Mg, Monthly	Not Reported
	Actemra	S	Unknown	360 Mg, Monthly	Not Reported
	Actemra	S	Unknown	380 Mg, Unknown	Not Reported
	Actemra	S	Unknown	360 Mg, Monthly	Not Reported
	Alendronate Sodium	S	Unknown	70 Mg, Weekly	Not Reported
	Alendronate Sodium	S	Unknown	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Mg, Freq: 2 X 1 Week	Not Reported
	Enbrel	S	Unknown	50 Mg, Freq: 2 X 1 Week, Biw	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	50 Mg, Weekly	Not Reported
	Humira	S	Subcutaneous	40 Mg, Freq: 1 X 2 Weeks, Qow	Not Reported
	Humira	S		40unk, Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg Qow	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg	Not Reported
	Methotrexate	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Weekly	Not Reported
	Methotrexate	S	Unknown	15 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg, Weekly	Not Reported
	Methotrexate	S	Unknown	12 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Weekly	Not Reported
	Methotrexate	S	Oral	10 Mg, Q4w	Not Reported
	Methotrexate	S	Unknown	12.5 Mg,Q4w	Not Reported

Methotrexate	S	Subcutaneous	15 Mg, Weekly	Not Reported
Methotrexate	S	Oral	10 Mg Q4w	Not Reported
Methotrexate	S	Unknown	10 Mg, Weekly	Not Reported
Methotrexate	S	Subcutaneous	10 Mg, Weekly	Not Reported
Methotrexate	S	Subcutaneous	17.5 Mg, Weekly	Not Reported
Methotrexate	S	Unknown	12.5 Mg, Weekly	Not Reported
Methotrexate	S	Unknown	10 Mg, Weekly	Not Reported
Methotrexate	S	Oral	10 Mg, Weekly	Not Reported
Methotrexate	S	Unknown	12.5 Mg, Weekly	Not Reported
Methotrexate	S	Unknown	12 Mg	Not Reported
Methotrexate	S	Oral	10 Mg Q4w	Not Reported
Methotrexate	S	Subcutaneous	12 Mg, Weekly	Not Reported
Methotrexate	S	Unknown	12.5 Mg, Weekly	Not Reported
Methotrexate	S	Unknown	10 Mg, Weekly	Not Reported
Methotrexate	S	Subcutaneous	15.5 Mg, Weekly	Not Reported
Methotrexate	S	Subcutaneous	12 Mg, Weekly	Not Reported
Methotrexate	S	Subcutaneous	70 Mg, Weekly	Not Reported
Methotrexate	S	Subcutaneous	10 Mg, Weekly	Not Reported
Methotrexate	S	Subcutaneous	12.5 Mg, Weekly	Not Reported
Methotrexate	S	Unknown	17.5 Mg, Weekly	Not Reported
Methotrexate	S	Unknown	15 Mg Q4w	Not Reported
Methotrexate	S	Unknown	12 Mg Q4w	Not Reported
Methotrexate	S	Subcutaneous	17.5 Mg Q4w	Not Reported
Methotrexate	S	Unknown	17 Mg, Weekly	Not Reported
Methotrexate	S	Unknown	12.5 Unk, Q4w	Not Reported
Orencia	S	Unknown	780 Mg, Weekly	Not Reported
Orencia	S	Unknown	780 Mg, Unknown	Not Reported
Orencia	S	Unknown	780 Mg, Weekly	Not Reported
Orencia	S	Intravenous (not	Unk	Not Reported

		otherwise specified)		
Remicade	S	Intravenous (not otherwise specified)	Unk, Powder And Solvent For Intravesical Suspension	Not Reported
Remicade	S	Unknown	, Powder And Solvent For Intravesical Suspensionunk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Mg	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Monthly Strength :50 Mg/Ml	Not Reported
Myochrysine	S	Intramuscular	25 Mg, Monthly	Not Reported
Myochrysine	S	Parenteral	50 Mg, Monthly	Not Reported
Myochrysine	S	Intramuscular	25 Mg, Weekly	Not Reported
Methotrexate Sodium	S	Oral	10 Mg, Qow	Not Reported
Alendronic Acid	S	Unknown	70 Mg, Weekly	Not Reported
Rituximab	S	Unknown	1000 Mg, Bid	Not Reported
Tocilizumab	S	Unknown	680 Mg Q4w	Not Reported
Ciclosporin	C		Unk	Not Reported
Prednisolone	C			Not Reported
Prednisone	C		Unk	Not Reported
Prednisone	C		Unk	Not Reported
Xeljanz	C			Not Reported
Alendronate Sodium	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	16859793	EXPEDITED (15-DAY)		OT	CA-ROCHE-1844081		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Diastolic Abnormal; Blood Pressure Fluctuation; Blood Pressure Increased; Diarrhoea; Heart Rate Increased; Hypertensive Crisis; Nausea; Pneumonia; Pneumonitis; Vomiting	Rituxan			S	Intravenous (not otherwise specified)	Last Infusion: 29/May/2019		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Arava			C				Not Reported
	Prednisone			C				Not Reported
	Effexor			C				Not Reported
	Tylenol			C	Oral			Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			C	Oral			Not Reported
	Solumedrol			C	Intravenous (not otherwise specified)			Not Reported
	Vit D			C				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	16878971	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2569757-00		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo Hydroxyquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Desoximetasone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17002427	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-E2B_00008027			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Breast Cancer; Breast Cancer Stage Iii; Condition Aggravated; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Drug Ineffective; Drug Intolerance; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Nausea; Ovarian Cancer; Rheumatoid Arthritis; Rheumatoid Nodule; Sleep Disorder; Therapeutic Product Effect Incomplete; Treatment Noncompliance	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unknown		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Hydroxychloroquine Sulfate		Concordia
	Arava			S	Unknown	Unknown		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unknown		Not Reported
	Sodium Aurothiomalate			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Methotrexate Bellon			S	Subcutaneous	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown Iv Nos		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported

	Methotrexate			S	Subcutaneous	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17030139	EXPEDITED (15-DAY)		OT	CA-ROCHE-2461478		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Oral			Not Reported
	Depo-Medrol			C				Not Reported
	Diclofenac			C				Not Reported
	Pantoprazole Magnesium			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17633498	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20160217144			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Drug Ineffective; Hip Fracture; Intervertebral Disc Disorder; Nausea; Rheumatoid Arthritis; Stress Fracture; Vomiting	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17656876	EXPEDITED (15-DAY)		LT	US-PFIZER INC-2020148479		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Electrocardiogram Qt Prolonged; Ventricular Fibrillation	Azithromycin			S	Oral	500 Mg, Daily (500 Mg On Day 1)		Pfizer
	Azithromycin			S	Oral	250 Mg, Daily (Followed By 250 Mg Daily For 4 Days)		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, 2x/Day (400 Mg Twice Daily On Day 1)		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day (Followed By 400 Mg Daily For 4 Days)		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 G, 1x/Day		Not Reported

U.S. FOOD & DRUG ADMINISTRATION

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17687062	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013397		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Hypertension; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor	Apo-Prednisone			S	Oral	Unk		Apotex
	Apo-Hydroxyquine			S	Oral	400 Mg, Qd		Apotex
	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Hydroxyquine			S	Oral	Unk		Apotex
	Cetirizine			S	Unknown	Unk		Apotex
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Diclofenac			S	Unknown	50 Mg, Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Acetaminophen			S	Unknown	Unk		Apotex
	Apo Folic Acid			S	Unknown	0.5 Mg, Unk		Not Reported
	Apo Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Apo Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Apo Folic Acid			S	Oral	25 Mg, Unk		Not Reported
	Winpred			S	Oral	Unk		Apotex
	Alendronate			S	Unknown	Unk		Apotex
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Sulfasalazine			S	Oral	1 G, Unk		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	Unk Unk, Bid		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	400 Mg, Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Cortisone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	4omg/0.8ml	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	4 Mg, Unk	Not Reported
	Methotrexate	S	Oral	25 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	20 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	20 Mg, Qd	Not Reported
	Methotrexate	S	Intra-arterial	25 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Reactine /00884302/	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported

Desoximetasone	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride W/Pseudoephedrine Hy	S	Unknown	Unk	Not Reported
Cortisone Acetate	S	Topical	25 Mg, Unk	Not Reported
Cortisone Acetate	S	Topical	Unk	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Topicort Lp	S	Subcutaneous	Unk	Not Reported
Topicorte	S	Subcutaneous	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
Plaquenil /00072602/	S	Unknown	400 Mg, Unk	Not Reported
Xeljanz	S	Unknown	5 Mg, Bid	Not Reported
Etanercept	S	Unknown	Unk	Not Reported
Salazopyrine	S	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Unk	Not Reported
Topicort /00028604/	S	Oral	Unk	Not Reported
Rituximab;Vorhyaluronidase Alfa	S	Subcutaneous	Unk	Not Reported
Cortisone Acetate	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Diclofenac	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17729811	EXPEDITED (15-DAY)		DE, OT	ES-PFIZER INC-2020171785		21 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hepatitis; Hypocoagulable State; Off Label Use; Pancreatitis Acute; Product Use In Unapproved Indication	Linezolid			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Ambisome [Amphotericin B]			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17740634	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017728		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Hydroxychloroquine			S	Oral	200 Mg, Bid		Apotex
	Apo-Acetaminophen			S	Unknown	325 Mg, Unk		Apotex
	Acetaminophen			S	Unknown	325 Mg, Unk		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Q.M.T.		Apotex
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Enbrel			S	Unknown	40 Mg, Q.I.W		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk. Therapy Duration 823 Unit Unspecified		Not Reported
	Enbrel			S	Unknown	50 Mg, Qd		Not Reported
	Enbrel			S	Unknown	40 Mg, Q.Wk.		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported

Cimzia	S	Subcutaneous	Unk	Not Reported
Simponi	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Unknown		Not Reported
Orencia	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	2000 Mg, Unk	Not Reported
Sulfasalazine	S	Oral	200 Mg, Unk	Not Reported
Tylenol /00020001/	S	Unknown	2000 Mg, Unk	Not Reported
Acetaminophen W/Diphenhydramine Hydrochloride	S	Unknown	Unk	Not Reported
Acetaminophen With Codeine	C	Unknown	Unk	Not Reported
Meloxicam	C	Unknown	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Methotrexate	C	Unknown	25 Mg, Q.Wk.	Not Reported
Acetaminophen And Codeine	C	Unknown	Unk	Not Reported
Celecoxib	C	Unknown	Unk	Not Reported
Hydromorphone Hcl	C	Unknown	Unk	Not Reported
Celebrex	C	Oral	200 Mg, Q.12h	Not Reported
Codeine	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17741494	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020171727		28 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated;	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer

Hepatitis; Off Label Use; Product Use In Unapproved Indication	Dolquine	S	Oral	400 Mg, 1x/Day	Not Reported
	Ceftriaxone	S	Intravenous (not otherwise specified)	2 G, 1x/Day	Not Reported
	Ceftriaxone	S			Not Reported
	Paracetamol	S	Intravenous (not otherwise specified)	1 G, 3x/Day (Every 8 Hours)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17776859	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1233507		27 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Rash	Azitromicina (7019a)			S	Oral	250 Milligram Daily;		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Nordimet 22,5 Mg Solucion Inyectable En Pluma Precargada, 4 Plumas Pre			C	Subcutaneous	1 Iny Sc On Monday		Not Reported
	Isdiben 20 Mg Capsulas Blandas , 50 Cápsulas			C	Oral	1 Cp Every 48 Hours, 20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17835105	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200528683		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Pneumonia; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Sulfasalazine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17845829	EXPEDITED (15-DAY)		DS	CA-ROCHE-2606963		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Disability; Disease Recurrence; Drug Ineffective; Dyspnoea; Impaired Work Ability; Infection; Insomnia; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Off Label Use; Pain; Peripheral Swelling; Physical Disability; Rash; Rheumatoid Arthritis; Skin Mass; Sleep Disorder; Therapeutic Product Effect Decreased; Therapy Non-Responder	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Ergocalciferol	C		Not Reported
	Risedronate Sodium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17845832	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606678		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Breast Cancer; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Infection; Intentional Product Use Issue; Joint Swelling; Loss Of Consciousness; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Endocervical	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Meloxicam	C		Not Reported
	Simponi	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17848609	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606875			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Rituxan			S	Unknown			Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Arava	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17853947	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-249092		77 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Injury; Off Label Use; Pruritus; Purpura; Rash	Azithromycin			S	Oral	1 Dosage Form, Daily		Sun
	Plaquenil			S	Oral	400 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17862547	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243676			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pulmonary Toxicity	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17862613	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243656			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Kevzara			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Acetaminophen			C	Unknown	1300 Milligram Daily;		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Aluminum Acetate			C	Unknown			Not Reported
	Atacand			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydrodiuril			C	Unknown			Not Reported
	Neurontin			C	Unknown	1800 Milligram Daily;		Not Reported

	Premarin			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17862918	EXPEDITED (15-DAY)		DS	CA-ROCHE-2609114		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1.0 Months		Not Reported
	Adalimumab			S	Subcutaneous	4.0 Years		Not Reported
	Etanercept			S	Unknown	404.0 Days		Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	5.0 Years		Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17863062	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3432027-00		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperbilirubinaemia; Long Qt Syndrome	Lopinavir/Ritonavir			S	Oral	200 Mg/50 Mg Comprimido		Not Reported
	Lopinavir/Ritonavir			S	Oral			Not Reported
	Hidroxicloroquina			S	Oral			Not Reported
	Hidroxicloroquina			S	Oral			Not Reported
	Hidroxicloroquina			S	Oral			Not Reported
	Azitromicina			S	Unknown			Not Reported
	Atorvastatina			C	Oral			Not Reported
	Telmisartan/Hidroclorotiazida Alter			C	Oral			Not Reported
	Metformina			C	Oral	50 Tablet		Not Reported
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17863097	EXPEDITED (15-DAY)		OT	CA-ROCHE-2610150		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Pressure Fluctuation; Body Height Decreased; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Irritable Bowel Syndrome; Off Label Use	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Esomeprazole	C	Unknown	Not Reported
	Esomeprazole Sodium	C	Unknown	Not Reported
	Lumigan Rc	C	Ophthalmic	Not Reported
	Pseudoephedrine Hydrochloride	C	Unknown	Not Reported
	Trazodone	C	Unknown	Not Reported
	Valsartan	C	Unknown	Not Reported
	Valsartan	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17863226	EXPEDITED (15-DAY)		OT	CA-ROCHE-2610708		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Product Use Issue; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Risedronate Sodium			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17863327	EXPEDITED (15-DAY)		DS	CA-ROCHE-2611039			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Azathioprine			C	Unknown			Not Reported
	Imuran [Azathioprine]			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17863361	NON-EXPEDITED			NVSC2020US156006			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17863699	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202005005271			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17863733	EXPEDITED (15-DAY)		OT	CA-ROCHE-2611796		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Stress	Rituximab			S	Intravenous drip	3.0 Months		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	4.0 Months		Not Reported
	Enbrel			S	Subcutaneous	7.0 Months; 1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	5.0 Months		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	5.0 Months		Not Reported
	Methotrexate			S	Unknown	4.0 Months		Not Reported
	Methotrexate			S	Oral	4.0 Months		Not Reported
	Orencia			S	Unknown	6.0 Months		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	5.0 Months		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17863740	EXPEDITED (15-DAY)		OT	CA-SA-2020SA142059			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Arthropathy; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Desoximetasone	S	Oral		Sanofi
	Diclofenac Sodium	S			Not Reported
	Leflunomide	S	Oral		Sanofi
	Cortisone Acetate	S			Not Reported
	Folic Acid	S			Not Reported
	Plaquenil	S	Oral	1 Df, Qd	Sanofi
	Sulfasalazine	S	Oral	1 G, Qd	Not Reported
	Cetirizine Hydrochloride	S			Not Reported
	Hydroxychloroquine Sulfate	S			Sanofi
	Methotrexate	S	Oral	25 Mg	Not Reported
	Alendronate Sodium	S	Oral		Not Reported
	Prednisone	S			Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Actemra	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Hydroxychloroquine	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17863809	EXPEDITED (15-DAY)		OT	CA-ROCHE-2611577			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatitis; Inflammation; Joint	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported

Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Adalimumab		S	Subcutaneous	Not Reported
	Apo-Leflunomide		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17863889	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042794		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Remicade			S	Unknown	5 Milligram/Kilogram		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17863916	EXPEDITED (15-DAY)		OT	CA-ROCHE-2143212		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis; Synovitis; Throat Tightness	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			C	Unknown			Not Reported
	Supeudol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17864008	EXPEDITED (15-DAY)		HO, OT	BN-IPCA LABORATORIES LIMITED-IPC-2020-BN-001787			Unknown	BRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Right; Electrocardiogram Qt Prolonged; Hypocalcaemia	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Ipca
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Ipca
	Lopinavir/Ritonavir			C	Unknown	500 Milligram, Bid		Not Reported
	Tamiflu			C	Unknown	75 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17864149	NON-EXPEDITED		OT	NL-AMGEN-NLDSP2020087555			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Haemolytic Anaemia	Enbrel	S	Unknown	Unk		Amgen
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17864270	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243816			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Neutropenia; Off Label Use; Osteoarthritis; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Therapy Partial Responder; Urinary Tract Infection	Methotrexate			S	Subcutaneous	15 Mg, Cyclical		Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			C	Subcutaneous			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17864276	EXPEDITED (15-DAY)		HO, OT	BN-IPCA LABORATORIES LIMITED-IPC-2020-BN-001788			Unknown	BRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Ipca
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Ipca
	Lopinavir/Ritonavir			C	Unknown	500 Milligram, Bid		Not Reported
	Tamiflu			C	Unknown	75 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17864406	EXPEDITED (15-DAY)		DS	CA-ROCHE-2610750		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Drug Ineffective; Drug Intolerance; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Gold (198 Au) Colloidal			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Indocid [Indometacin]			S	Unknown			Not Reported
	Indometacin			S	Unknown			Not Reported
	Indometacin			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

			otherwise specified)	
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Cymbalta	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17864512	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1243643		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Headache; Hepatic Cyst; Hepatic Haematoma; Hepatitis B Core Antibody Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Neutropenia; Pulmonary Mass; Pyrexia; Renal Cyst	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Isoniazid			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2000 Milligram Daily;		Not Reported
	Zostavax			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17864636	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609924		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Amlodipine Besilate			S	Oral			Not Reported
	Asacol			S	Unknown			Not Reported
	Diamicron			S	Unknown			Not Reported

Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Enbrel	S	Subcutaneous	Not Reported
	Gliclazide	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Tylenol	C		Not Reported
	Rosuvastatin Calcium	C		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
	Folic Acid	C		Not Reported
	Ferrous Gluconate	C		Not Reported
	Ebastine	C		Not Reported
	Diphenhydramine	C	Oral	Not Reported
	Acetaminophen	C	Oral	Not Reported
	Atacand Plus	C	Unknown	Not Reported
	Bisoprolol Fumarate	C		Not Reported
	Depo-Medrol	C	Intra-articular	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17864847	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020217978			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swollen Joint Count Increased; Tender Joint Count Increased	Methotrexate Sodium			S	Unknown	15 Mg		Pfizer
	Celebrex			S	Oral	100 Mg, Twice Daily		Pfizer
	Folic Acid			S	Oral	1 Mg, Once Daily		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Once Daily		Not Reported
	Leflunomide			S	Unknown	10 Mg		Not Reported
	Naproxen			S		500 Mg, Twice Daily		Not Reported

Ergocalciferol	C	Oral	25 Ug, Once Daily		Not Reported
Lansoprazole	C	Oral	30 Mg, Once Daily		Not Reported
Paroxetine Hydrochloride	C	Oral	20 Mg, Once Daily		Not Reported
Prazosin Hydrochloride	C	Oral	2 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17864865	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2020M1053810		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Covid-19; Pyrexia	Prednisone			S		8 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17864872	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170817785		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Osteoarthritis; Synovitis	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865021	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1244040			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Malaise; Multiple Sclerosis; Nausea; Vomiting	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865055	EXPEDITED (15-DAY)		CA, OT	CA-TEVA-2020-CA-1243644			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anaemia Of Chronic Disease; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Haemodilution; Headache; Hepatic Cyst; Hepatic Haematoma; Interferon Gamma Release Assay Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Musculoskeletal Stiffness; Neutropenia; Pulmonary Fibrosis; Pulmonary Mass; Pyrexia; Renal Cyst; Thalassaemia	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Celebrex			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Isoniazid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865056	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243647		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Cervical Vertebral Fracture; Drug Ineffective; Drug Ineffective; Drug Interaction; Drug Intolerance; Grip Strength Decreased; Hypophagia; Influenza; Joint Range Of Motion Decreased; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nausea; Rheumatoid Arthritis; Upper Limb Fracture; Vomiting	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865058	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1244123			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C				Not Reported
	Lyrica			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865064	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-044295		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Joint Swelling; Pneumonia; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Plaquenil S			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865418	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243990			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865433	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-044300			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Q4wk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Bid		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Methotrexate			S	Subcutaneous	17 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865440	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243861			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate			S	Other			Barr
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Celebrex	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865447	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1244124			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Metals; Arthralgia; Arthropathy; Blood Cholesterol Increased; Gastric Disorder; Granuloma; Pain In Extremity; Pruritus; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased; Skin Wrinkling; Spinal Osteoarthritis; Therapeutic Product Effect Decreased; Thyroid Disorder	Methotrexate			S	Unknown			Barr
	Celebrex			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865496	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243991			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Malaise; Multiple Sclerosis; Vomiting	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Acetaminophen			C				Not Reported
	Cannabis Sativa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865703	EXPEDITED (15-DAY)		DS	CA-SA-2020SA142122			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Pregnancy; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Topicort			S	Cutaneous			Sanofi
	Desoximetasone			S	Oral			Sanofi
	Diclofenac Sodium			S				Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Hydroxychloroquine Sulfate			S	Oral			Sanofi
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Prednisone			S				Not Reported
	Prednisone			S	Oral			Not Reported
	Arava			S	Oral			Sanofi
	Leflunomide			S	Oral			Sanofi
	Cetirizine Hydrochloride			S		10 Mg		Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S		10 Mg		Not Reported
	Cortisone Acetate			S	Topical	25 Mg		Not Reported
	Folic Acid			S		5 Mg		Not Reported
	Folic Acid			S		5 Mg		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg, Qd		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Sanofi
	Alendronate Sodium			S	Oral			Not Reported
	Sulfasalazine			S	Oral	2000 Mg (1000 Mg,2 In 1 D)		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Cimzia			S				Not Reported

Enbrel	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous	40 Mg	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Tofacitinib Citrate	S	Unknown	5 Mg, 2 In 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865792	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA142257			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Hydroxychloroquine			S	Oral	200 Mg, Bid		Sanofi
	Arava			S	Oral	20 Mg		Sanofi
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Prednisone			S	Oral	1 Df, Qd		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, Bid		Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Humira			S	Subcutaneous	20 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Actemra			S				Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865875	NON-EXPEDITED			US-PFIZER INC-2020220001		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Xeljanz			S		Unk		Pfizer
	Plaquenil Sulfate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866034	EXPEDITED (15-DAY)		OT	NVSC2020CA156639			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy	Cosentyx			S	Unknown	Unk		Novartis
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous drip	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866127	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-044401			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort;	Orencia			S	Unknown			Bristol Myers Squibb

Rheumatoid Arthritis; Treatment Failure	Adalimumab	S	Subcutaneous	40 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tofacitinib	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Rabeprazole Sodium	C	Oral	20 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866259	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1244491		46 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Pain	Hidroxicloroquina Ratiopharm 200 Mg Co Mprimidos Recubiertos Con Pelicu			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866347	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-18737			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug	Etanercept			S	Unknown	Unknown		Not Reported

Ineffective; Red Blood Cell Sedimentation Rate Increased	Enbrel	S	Unknown			Not Reported
	Gold/Hyoscyamus Niger/Onopordum Acanthium/Primula Veris [Homeopathic]	S	Unknown	Unknown		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S	Unknown	Unknown		Not Reported
	Plaquenil	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866428	EXPEDITED (15-DAY)		DE, HO, OT	ES-009507513-2006ESP000064		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Atrial Fibrillation; Cardiac Failure; Death; Product Use In Unapproved Indication; Pyrexia; Renal Failure; Respiratory Failure	Ertapenem Sodium			S		Unk		Merck
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Lopinavir (+) Ritonavir			S		Unk		Not Reported
	Lopinavir (+) Ritonavir			S				Not Reported
	Lopinavir (+) Ritonavir			S				Not Reported
	Azithromycin			S		Unk		Not Reported
	Azithromycin			S				Not Reported
	Azithromycin			S				Not Reported
	Methylprednisolone Acetate			S		Unk		Not Reported
	Methylprednisolone Acetate			S		Lower Doses (+/- 1mg/Kg Per Day)		Not Reported
	Methylprednisolone Acetate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866550	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243645			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug	Methotrexate			S	Unknown			Barr

Intolerance; Rash; Therapeutic Response Decreased; Therapy Non-Responder	Actemra		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866551	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243650			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Head Injury; Road Traffic Accident	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866553	EXPEDITED (15-DAY)		CA	CA-TEVA-2020-CA-1243636		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Mood Swings; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Indometacin			S	Unknown			Actavis
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported
	Apo-Prednisone			S	Oral	25 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Cymbalta	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866559	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243686		68 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Fatigue; Feeling Abnormal; Immunodeficiency; Impaired Quality Of Life; Joint Swelling; Nausea; Paralysis; Polymyalgia Rheumatica; Somnolence; Synovitis; Wrist Surgery	Methotrexate			S	Unknown			Barr
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Desoximetasone			S	Unknown	4 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866562	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243694			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Fluid Retention; Joint Swelling; Memory Impairment; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866584	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1244079			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Hypoaesthesia; Joint Swelling; Malaise; Multiple Sclerosis; Musculoskeletal Disorder; Nausea; Vomiting	Methotrexate			S	Other			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Codeine			C				Not Reported
	Lyrica			C				Not Reported
	Prednisone			C	Oral	15 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866883	EXPEDITED (15-DAY)		HO	CA-ROCHE-2612220		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine	S		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866903	EXPEDITED (15-DAY)		DE	LU-ELI_LILLY_AND_COMPANY-LU202006001577		83 YR	Female	LUX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Tachycardia	Zyprexa			S	Oral	5 Mg, Daily		Eli Lilly And Co
	Tiapridal			S	Oral	50 Mg, Daily		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, Bid		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, Bid		Not Reported
	Aprovel			C	Oral	150 Mg, 12 Hours		Not Reported
	Tazobactam			C	Intravenous (not otherwise specified)	4 G, Every 8 Hrs		Not Reported
	Doxycycline			C	Oral	100 Mg, Bid		Not Reported
	Trajenta			C	Oral	5 Mg, Daily		Not Reported
	Levemir			C	Subcutaneous	12 International Unit, Daily		Not Reported

	Dafalgan	C	Oral	1 G, Every 6 Hrs In Case Of Fever	Not Reported
	Metoprolol Eg [Metoprolol Succinate]	C	Oral	100 Mg, Every 12 Hours	Not Reported
	Mirapexin	C	Oral	0.18 Mg, Every 12 Hours	Not Reported
	Clexane	C	Subcutaneous	40 Mg, Daily	Not Reported
	Piperacillin	C	Intravenous (not otherwise specified)	4 G, Every 8 Hrs	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866938	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-044382		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Rheumatoid Factor Positive; Spinal Column Injury; Synovitis; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866952	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1243641		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive;	Methotrexate			S	Unknown			Barr

Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Arthrotec	C	Unknown		Not Reported
	Azathioprine	C			Not Reported
	Ergocalciferol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866998	EXPEDITED (15-DAY)		LT, OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2020VAL000465			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Pulmonary Embolism	Furosemide			S	Oral	40 Mg, Qd		Validus
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Not Reported
	Enoxaparin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17867038	NON-EXPEDITED			US-PFIZER INC-2020216868		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Hypersensitivity	Effexor			S		Unk		Pfizer
	Lidocaine Hcl			S		Unk		Pfizer
	Lyrica			S		Unk		Pfizer
	Amitiza			S		Unk		Not Reported
	Chlorhexidine			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Fluzone (Subvirion)			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported
	Salagen			S		Unk		Not Reported
	Tdap			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17867269	EXPEDITED (15-DAY)		OT	CH-MALLINCKRODT-T202002543		51 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Hepatocellular Injury; Hypoxia	Ofirmev			S	Intravenous (not otherwise specified)	1 Milligram, Prn		Mallinckrodt
	Augmentin			S	Intravenous drip	1.2 Gram		Not Reported
	Plaquenil			S	Oral	800 Milligram (In Total)		Not Reported
	Kaletra			S	Oral	400 Milligram		Not Reported
	Kaletra			S	Oral	400 Milligram		Not Reported
	Clexane			S	Subcutaneous	40 Milligram		Not Reported
	Clexane			S	Subcutaneous	40 Milligram		Not Reported
	Clexane			S	Subcutaneous	Unk		Not Reported
	Clexane			S	Subcutaneous	40 Milligram		Not Reported
	Piperacilline/Tazobactam			S	Intravenous drip	Unk		Not Reported
	Zithromax			S	Oral	500 Milligram		Not Reported
	Ipramol			C	Unknown	Unk		Not Reported

Temesta	C	Unknown	Unk		Not Reported
Tavanic	C	Unknown	Unk		Not Reported
Atracurium	C	Unknown	Unk		Not Reported
Fentanyl	C	Unknown	Unk		Not Reported
Dormicum	C	Unknown	Unk		Not Reported
Phosphate	C	Unknown	Unk		Not Reported
Torasemide	C	Unknown	Unk		Not Reported
Potassium	C	Unknown	Unk		Not Reported
Benerva	C	Unknown	Unk		Not Reported
Heparin	C	Unknown	Unk		Not Reported
Solu-Medrol	C	Unknown	Unk		Not Reported
Novorapid	C	Unknown	Unk		Not Reported
Relistor	C	Unknown	Unk		Not Reported
Novasource Gi Control	C	Unknown	Unk		Not Reported
Ventoline	C	Unknown	Unk		Not Reported
Movicol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17867658	EXPEDITED (15-DAY)		OT	NVSC2020CA156677			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Drug Intolerance; Interstitial Lung Disease; Pulmonary Mass; Sinusitis; Synovitis; Treatment Failure	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk (Solution)		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17867699	EXPEDITED (15-DAY)		HO	ES-ROCHE-2613104		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab			S				Not Reported
	Hydroxychloroquine			S	Oral	400 Mg Dia		Not Reported
	Hydroxychloroquine			S				Not Reported
	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17867705	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3433903-00		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Hypertriglyceridaemia	Kaletra 200/50			S	Oral	Comprimidos Recubiertos Con Pelicula, 120 Comprimidos		Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17867957	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA154431		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unknown		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported

Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Naproxen	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Unknown	1 Df, Unknown	Not Reported
	Naproxen Sodium	S	Oral	Unk	Not Reported
	Naproxen Sodium	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Oral	5.0 Mg, Bid	Not Reported
	Apo-Naproxen	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone Acetate	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	12.5 Mg, Unknown	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid (2 Every 1 Day)	Not Reported
	Xeljanz	S	Oral	50 Mg, Unknown	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg (Solution)	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Insulin	C	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	2 Df, Qd (1 Every 1 Day)	Not Reported
	Metformin	C	Unknown	2 Df, Bid (2 Every 1 Day)	Not Reported

	Acetaminophen	C	Unknown	Unk		Not Reported
	Acetaminophen And Codeine	C	Unknown	Unk		Not Reported
	Folic Acid	C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17868098	EXPEDITED (15-DAY)		OT	CA-ROCHE-2611984		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Off Label Use; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17868155	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2607024		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Arthralgia; Arthritis; Arthropathy; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Creatinine Increased; Blood Parathyroid Hormone Decreased; Blood Pressure Systolic	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Apo-Cyclosporine			S	Unknown			Not Reported
	Apo-Cyclosporine			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Decreased Appetite; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Intolerance; Enthesopathy; Erythema; Fatigue; Fear Of Injection; General Physical Health Deterioration; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Insomnia; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Apo-Leflunomide	S	Oral	Not Reported
	Apremilast	S	Unknown	Not Reported
	Apremilast	S	Unknown	Not Reported
	Apremilast	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Celebrex	S	Oral	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Ciclosporin	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Codeine	S	Unknown	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Cyclosporin	S	Oral	Not Reported
	Abatacept	S	Unknown	Not Reported
	Abatacept	S		Not Reported
	Etanercept	S	Unknown	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Apo-Ibuprofen	S	Oral	Not Reported
	Ustekinumab	S	Oral	Not Reported
	Remicade	S	Subcutaneous	Not Reported
	Stelara	S	Unknown	Not Reported
	Stelara	S		Not Reported
	Stelara	S		Not Reported
	Sulfamethoxazole	S	Unknown	Not Reported
	Sulfamethoxazole	S		Not Reported
	Sulfamethoxazole	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Sulfasalazine	S		Not Reported
	Otezla	S	Unknown	Not Reported
	Otezla	S		Not Reported

	Otezla	S			Not Reported
	Motrin [Ibuprofen]	S	Unknown		Not Reported
	Motrin [Ibuprofen]	S	Oral		Not Reported
	Motrin [Ibuprofen]	S			Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S			Not Reported
	Leflunomide	S	Oral		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Ibuprofen	S	Oral		Not Reported
	Golimumab	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17868212	EXPEDITED (15-DAY)		OT	CA-ROCHE-2611791		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Intentional Product Misuse; Interstitial Lung Disease; Off Label Use	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Naproxen	C			Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17868216	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3433673-00		80 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome	Kaletra 200/50			S	Oral			Not Reported
	Dolquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17868228	EXPEDITED (15-DAY)		OT	CA-ROCHE-2611996		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Investigation Abnormal; Loss Of Personal Independence In Daily Activities; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Septra			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	15733751	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594183-00		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Humira		S	Subcutaneous	Not Reported
	Actemra		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Prednisone		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	16003920	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-TEVA-2019-CA-1017774		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Intra-arterial			Barr
	Methotrexate Sodium			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Minocycline			S	Unknown			Actavis
	Minocycline Hydrochloride			S	Unknown			Actavis
	Oxycodone			S	Unknown			Actavis
	Oxycodone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported

Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Ilaris Single-Use Vial	S	Unknown		Not Reported
	Ilaris Single-Use Vial	S	Subcutaneous		Not Reported
	Ilaris Single-Use Vial	S	Intravenous (not otherwise specified)		Not Reported
	Ilaris Single-Use Vial	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S			Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported

Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Sodium Aurothiomalate	S	Parenteral		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S			Not Reported
Gold	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Marijuana	S	Unknown		Not Reported
Rituximab	S	Unknown		Not Reported
Rituximab	S			Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Oxyquinoline Sulfate	S	Unknown		Not Reported
Oxyquinoline Sulfate	S			Not Reported
Rituximab/Urelumab	C	Unknown		Not Reported
Kineret	C	Unknown		Not Reported
Lyrica	C	Oral		Not Reported
Lyrica	C			Not Reported
Prednisone	C	Unknown	7 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	16075445	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-012854		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Arthralgia;	Alendronic Acid Tablets			S	Unknown	70 Milligram, 1 Every 1 Week		Aurobindo

Aspartate Aminotransferase; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Ulcer	Alendronic Acid	S	Unknown	70 Milligram, Every Week	Aurobindo
	Alendronic Acid	S	Unknown	Unk	Aurobindo
	Actemra	S	Unknown	360 Milligram, 1 Every Month	Not Reported
	Actemra	S	Unknown	680 Milligram, 1 Every 4 Weeks	Not Reported
	Actemra	S	Unknown	2.68 Milligram, 1 Every 4 Weeks	Not Reported
	Actemra	S	Unknown	680.0 Milligram, 1 Every 1 Month	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Ciclosporin	S	Unknown	150 Milligram, Once A Day	Not Reported
	Enbrel	S	Unknown	25 Milligram, 2 Every Week	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, Every Week	Not Reported
	Enbrel	S	Unknown	50 Milligram, Every Week	Not Reported
	Enbrel	S	Unknown	25.0 Milligram, 1 Every 2 Weeks	Not Reported
	Humira	S	Subcutaneous	40 Milligram, 1 Every 2 Weeks	Not Reported
	Hydroxychloroquine	S	Oral	20 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported

Leflunomide	S	Oral	Unk	Not Reported
Methotrexate	S	Oral	10 Milligram, Every Week	Not Reported
Methotrexate	S	Unknown	12 Milligram, Every Week	Not Reported
Methotrexate	S	Unknown	12 Milligram	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, Every Week	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, Every Week	Not Reported
Methotrexate	S	Subcutaneous	10.0 Milligram, Every Week	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
Methotrexate	S	Subcutaneous	12 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	70 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	10.0 Milligram, 1 Every 2 Weeks	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Subcutaneous	10.0 Milligram, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Unknown	10.0 Milligram, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Subcutaneous	15.5 Milligram, Every Week	Not Reported
Methotrexate	S	Oral	10.0 Milligram, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, 1 Every 1	Not Reported

			Week	
Methotrexate	S	Subcutaneous	70 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	12 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	15.5milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	17.5milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Oral	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Oral	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Oral	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	12.0 Milligram, Every Week	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, 1 Every 1 Month	Not Reported
Myochrysine	S	Parenteral	50.0 Milligram, 1 Every 1 Month	Not Reported
Orencia	S	Unknown	780 Milligram, Every Week	Not Reported
Orencia	S	Unknown	760 Milligram, 1 Every 1 Week	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, 2 Every 1 Day	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	360 Milligram, 1 Every 1 Month	Not Reported

	Tocilizumab	S	Unknown	380 Milligram	Not Reported
	Tocilizumab	S	Unknown	680.0 Milligram, 1 Every 4 Weeks	Not Reported
	Ciclosporin	C	Unknown	150 Milligram, Once A Day	Not Reported
	Prednisone	C	Unknown	10 Milligram, Once A Day	Not Reported
	Xeljanz	C	Unknown	5 Milligram, 2 Every 1 Day	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Prednisolone	C	Unknown	10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	16075446	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-012901			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25.0 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	1.0 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

Plaquenil	S	Oral	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Simponi	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sulfasalazine	S	Unknown	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	16075459	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-012877		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Product Use	Alendronic Acid Tablets			S	Unknown	70 Milligram, 1 Every Week		Aurobindo
	Actemra			S	Intravenous (not otherwise specified)	680 Milligram, 1 Every 4 Week		Not Reported
	Actemra			S	Unknown	360 Milligram, 1 Every Week		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	360 Milligram, 1 Every Month		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Every Week		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram, Every		Not Reported

Issue; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer				Week	
	Methotrexate	S	Oral	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram	Not Reported
	Methotrexate	S	Unknown	12 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	12 Milligram	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, 1 Every Month	Not Reported
	Orencia	S	Unknown	780 Milligram, Every Week	Not Reported
	Rituximab	S	Intravenous drip	1000 Milligram, Two Times A Day	Not Reported
	Methotrexate	S	Oral	10 Milligram, Every Week	Not Reported
	Ciclosporin	S	Unknown	150 Milligram, Once A Day	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	16387698	EXPEDITED (15-DAY)		DS, HO, OT	CA-AUROBINDO-AUR-APL-2019-029940		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive	Alendronic Acid Tablets			S	Unknown	70 Milligram, Every Week		Aurobindo
	Alendronic Acid Tablets			S	Unknown	70 Milligram, 4 Every Week		Aurobindo
	Actemra			S	Unknown	2.68 Milligram,Once Every 4 Weeks		Not Reported
	Actemra			S	Unknown	360 Milligram,Once In A		Not Reported

Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Response Decreased; Tongue Disorder; Ulcer				Month	
	Actemra	S	Unknown	360 Milligram, Every Week	Not Reported
	Actemra	S	Unknown	680 Milligram, 1 Every 4 Weeks	Not Reported
	Actemra	S	Unknown	360 Milligram,Once Every 4 Weeks	Not Reported
	Alendronate Sodium	S	Unknown	70 Milligram, Every Week	Not Reported
	Apo-Ibuprofen	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apremilast	S	Unknown	60 Milligram, Two Times A Day	Not Reported
	Apremilast	S			Not Reported
	Apremilast	S			Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	25 Milligram, 2 Every 1 Week (50 Milligram)	Not Reported
	Enbrel	S	Unknown	25 Milligram, 1 Every 2 Week	Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram, 1 Every 2 Weeks	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Ibuprofen	S	Oral	600 Milligram, Once A Day	Not Reported
	Infliximab	S	Oral	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	12.0 Milligram,Once In Aweek	Not Reported

Methotrexate	S	Subcutaneous	15.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, Every Week	Not Reported
Methotrexate	S	Subcutaneous	10.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	70.0 Milligram,Once In Aweek	Not Reported
Methotrexate	S	Subcutaneous	10.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram,Once In A Week	Not Reported
Methotrexate	S	Oral	10.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	12.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	10.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	10.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	15.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	10.0 Milligram,Once In A 2 Weeks	Not Reported
Methotrexate	S	Subcutaneous	15.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, Every Week	Not Reported

Methotrexate	S	Unknown	12.5 Milligram, 4 Every 1 Week	Not Reported
Methotrexate	S	Unknown	10.0 Milligram,4 Every 1 Year	Not Reported
Methotrexate	S	Unknown	12 Milligram, 4 Every 1 Week	Not Reported
Methotrexate	S	Unknown	17.5 Milligram, 4 Every 1 Week	Not Reported
Mogadon	S	Oral	5 Milligram	Not Reported
Myochrysine	S	Parenteral	50 Milligram,Once In A Month (Solution Intramuscular)	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Every Week	Not Reported
Nitrazepam	S	Oral	5 Milligram	Not Reported
Orencia	S	Unknown	780 Milligram,Once In A Week	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Otezla	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Two Times A Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Every Week	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Endocervical	500 Milligram	Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Tocilizumab	S	Unknown	380 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Ciclosporin	C	Unknown	Unk	Not Reported

Colchicine	C	Unknown	Unk		Not Reported
Dexilant	C	Oral	Unk		Not Reported
Febuxostat	C	Unknown	Unk		Not Reported
Folic Acid	C	Unknown	Unk		Not Reported
Gravol	C	Unknown	Unk		Not Reported
Oxycodone	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Uloric	C	Oral	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	16530325	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-212718		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Acute; Cardiotoxicity; Electrocardiogram Qt Prolonged; Electrocardiogram T Wave Inversion; Hypertensive Cardiomyopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17307005	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2020-003529		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product	Alendronic Acid Tablets			S	Oral	Unk		Aurobindo
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported

Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Pregnancy; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cetirizine Hcl / Pseudoephedrine Hcl	S	Unknown	10 Milligram	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Diclofenac	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400.0 Milligram, Once A Day	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Once A Day	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	400 Milligram, Once A Day	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported

Simponi	S	Subcutaneous	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Oral	1000 Milligram, Two Times A Day		Not Reported
Sulfasalazine	S	Oral	500 Milligram		Not Reported
Sulfathalidine	S	Oral	1000 Milligram, Two Times A Day		Not Reported
Sulfathalidine	S	Oral	500 Milligram		Not Reported
Tofacitinib	S	Unknown	5 Milligram, Two Times A Day		Not Reported
Tofacitinib Citrate	S	Unknown	5 Milligram, Two Times A Day		Not Reported
Topicort	S	Cutaneous	Unk		Not Reported
Atasol	C	Unknown	Unk		Not Reported
Salazopyrin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17768496	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3399487-00		70 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Diarrhoea; Off Label Use; Renal Impairment	Lopinavir/Ritonavir			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Linezolid			C	Intravenous (not otherwise specified)			Not Reported
	Meropenem			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17867902	EXPEDITED (15-DAY)		OT	CA-ROCHE-2610129			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Antinuclear Antibody Positive; Arthralgia; Arthritis; Blister; Dry Mouth; Headache; Hypersensitivity Vasculitis; Hypoaesthesia; Joint Swelling; Leukopenia; Lip Swelling; Lymphadenopathy; Menorrhagia; Musculoskeletal Stiffness; Myalgia; Nausea; Parotid Gland Enlargement; Peripheral Swelling; Rheumatoid Arthritis; Sjogren'S Syndrome; Systemic Lupus Erythematosus; Vasculitis	Rituximab	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Belimumab	S	Unknown		Not Reported
	Celebrex	S	Unknown		Not Reported
	Colchicine	S	Unknown		Not Reported
	Dexilant	S	Oral		Not Reported
	Estrogel	S	Topical		Not Reported
	Meloxicam	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Therapy Duration: 0.0	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ventolin Hfa	S	Other		Not Reported
	Breo Ellipta	S	Other		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17867908	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609861			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Naprosyn [Naproxen]			S	Oral			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Vioxx	S	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17867979	EXPEDITED (15-DAY)		OT	CA-ROCHE-2611810			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Epistaxis; Headache; Insomnia; Nausea; Osteonecrosis Of Jaw; Transaminases Increased	Rituximab			S	Intravenous drip			Not Reported
	Mycophenolate Mofetil			S	Oral			Not Reported
	Mycophenolate Mofetil			S	Oral	Therapy Duration 3.0 Months		Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Risedronate Sodium			S	Oral			Not Reported
	Azathioprine			C	Oral	Therapy Duration 2.0 Months		Not Reported
	Azathioprine			C	Oral	Therapy Duration 661.0 Days		Not Reported
	Azathioprine			C	Oral	Therapy Duration 5.0 Years		Not Reported
	Humira			C	Subcutaneous			Not Reported
	Ketoprofen			C	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Prolia			C	Subcutaneous	Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17868160	EXPEDITED (15-DAY)		OT	ES-ROCHE-2614539		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Roactemra			S	Intravenous (not otherwise specified)			Not Reported
	Roactemra			S				Not Reported
	Azitromicina			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17868359	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609764			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Bronchitis; Diarrhoea; Drug Ineffective; Dyspepsia; Fear; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Treatment Failure	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Actemra			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Enbrel			C				Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17868361	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609748		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis;	Rituximab			S	Intravenous drip			Not Reported

Dermatomyositis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Intentional Product Use Issue; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Pain; Thrombosis; Uterine Disorder; Weight Increased	Coumadin	S	Unknown		Not Reported
	Cymbalta	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Metformin	S	Unknown		Not Reported
	Metformin	S			Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xarelto	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17868411	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1244290			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17868531	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1244342			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity;	Methotrexate			S	Unknown	20 Mg, 1 Every 1 Week		Barr

Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Actemra	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Other	20 Milligram Daily;	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Sulfasalazine	S	Unknown	2 Milligram Daily;	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17868533	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1244238		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Body Height Decreased; Drug Ineffective; Flushing; Inflammation; Intentional Product Use Issue; Interstitial Lung Disease; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Unknown	3000 Milligram Daily;		Not Reported
	Esomeprazole			C	Unknown	40 Milligram Daily;		Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Lumigan Rc			C	Ophthalmic			Not Reported
	Lyrica			C	Unknown			Not Reported
	Sulfasalazin			C	Unknown	2000 Milligram Daily;		Not Reported
	Suphedrine [Pseudoephedrine Hydrochloride]			C	Unknown	10 Milligram Daily;		Not Reported

Trazodone	C	Unknown	200 Milligram Daily;		Not Reported
Valsartan	C	Unknown			Not Reported
Wellbutrin	C	Unknown	300 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17868536	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1244265			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Contraindicated Product Administered; Drug Intolerance; Maculopathy; Thrombocytopenia	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			C	Unknown	50 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2020	15934368	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2655903-00		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete;	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Benzalkonium Chloride			S	Unknown			Not Reported
	Boric Acid			S	Unknown			Not Reported
	Disodium Edetate			S	Unknown			Not Reported
	Phenylephrine Hydrochloride			S	Unknown			Not Reported
	Sodium Borate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rho D Immune Globulin			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported

Therapy Non-Responder; Treatment Failure	Arava	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Simponi	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Celebrex	C	Oral	Not Reported
	Ibuprofen	C	Oral	Not Reported
	Lipitor	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Sulfasalazine	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2020	17359996	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533770		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Bone Hypertrophy; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 2 Years		Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	Therapy Duration: 5 Years		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported

Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Intentional Product Use Issue; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Off Label Use; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Treatment Failure	Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 330 Days	Not Reported
	Orencia	S			Not Reported
	Oxycontin	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S			Not Reported
	Nortriptyline Hydrochloride	S	Oral		Not Reported
	Nortriptyline Hydrochloride	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Apo-Gabapentin	S	Oral		Not Reported
	Celecoxib	S	Oral		Not Reported
	Celecoxib	S	Oral		Not Reported
	Calcium	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown		Not Reported
	Nasonex	C	Unknown		Not Reported
	Omega-3 Fatty Acids	C	Unknown		Not Reported
	Oxycodone Terephthalate	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Trazodone Hydrochloride	C	Oral		Not Reported
	Tylenol	C	Oral		Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C			Not Reported
	Aclasta	C			Not Reported

	Actonel			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2020	17821555	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-247051		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Foetal Growth Restriction; Premature Delivery	Prednisone			S	Unknown	Unk		Sun
	Insulin			S	Unknown	Unk		Not Reported
	Aspirin			S	Unknown	Unk		Sun
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2020	17868879	EXPEDITED (15-DAY)		OT	CA-ROCHE-2611587		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

	Risedronate Sodium	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Tylenol	C		Not Reported
	Cyclobenzaprine	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Prednisone Acetate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2020	17868884	EXPEDITED (15-DAY)		OT	ES-ROCHE-2612860		47 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S				Not Reported
	Dexketoprofeno [Dexketoprofen]			S	Intravenous (not otherwise specified)			Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported
	Hidroxicloroquina Sulfato			S				Not Reported
	Azitromicina			S	Oral			Not Reported
	Azitromicina			S				Not Reported
	Paracetamol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2020	17868903	EXPEDITED (15-DAY)		HO	ES-ROCHE-2613270		56 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S				Not Reported

	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S		Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Azitromicina	S	Oral	Not Reported
	Azitromicina	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	12769487	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-015683			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Glucose Increased; Blood Pressure Increased; C-Reactive Protein Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Femur Fracture; Gait Disturbance; Gastric Disorder; Glycosylated Haemoglobin Increased; Heart Rate Increased; Hepatic Enzyme Increased; Hospitalisation; Infection; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphocyte Count Increased; Malaise; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Nausea; Nephrolithiasis; Neutrophil Count Increased;	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Unknown	200 Milligram		Bristol Myers Squibb
	Tylenol			S	Unknown	As Needed		Not Reported
	Enbrel			S	Unknown	50 Mg, Qwk(Loe)		Not Reported
	Enbrel			S	Unknown	40 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qd		Not Reported
	Sulfasalazine			S	Oral	2000 Mg(Intolerance)		Not Reported
	Sulfasalazine			S	Unknown	2 Gram		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram, Qd		Not Reported
	Sulfasalazine			S	Oral	200 Unk (6 Months)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	800 Milligram		Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Acetaminophen			S	Unknown	325 Milligram		Not Reported
	Acetaminophen			S	Unknown	Unk		Not Reported
	Apo Hydro			S	Unknown	Unk		Not Reported

Osteopenia; Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Product Use Issue; Pyrexia; Rash; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Somnolence; Synovitis; Therapeutic Product Effect Incomplete; Tooth Abscess; Treatment Failure; Visual Impairment; Weight Decreased; White Blood Cell Count Increased	Simponi	S	Subcutaneous		Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	200 Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	200 Mg, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, 1 Every 24 Hours	Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Milligram, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	200 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	5 Unit	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Subcutaneous	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Acetaminophen	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram, Bid	Not Reported
	Doxycycline	S	Unknown	100 Milligram, Bid	Not Reported
	Acetaminophen And Codeine Phosphate	S	Unknown	Unk	Not Reported
	Acetaminophen;Diphenhydramine Hydrochloride	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown	20 Nanogram	Not Reported
	Diphenhydramine Hydrochloride;Paracetamol	S	Unknown	Unk	Not Reported

Xeljanz	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	20 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	25 Dosage Form	Not Reported
Methotrexate	S	Unknown	Unk, Qwk	Not Reported
Meloxicam	C	Unknown		Not Reported
Synthroid	C	Unknown		Not Reported
Tylenol W/Codeine	C	Unknown		Not Reported
Celebrex	C	Oral	200 Mg, Bid	Not Reported
Hydromorphone Hydrochloride	C	Unknown		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Celecoxib	C	Unknown		Not Reported
Codeine	C	Unknown		Not Reported
Leflunomide	C	Unknown	20 Milligram, 2 Every 1 Day	Not Reported
Diphenhydramine	C	Oral	50 Milligram	Not Reported
Glyburide (Micronized)	C	Unknown	Unk	Not Reported
Hydrochlorothiazide	C	Unknown	Unk	Not Reported
Lipitor [Atorvastatin]	C	Unknown		Not Reported
Metormin	C	Unknown		Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
Percocet [Oxycodone Hydrochloride;Paracetamol]	C	Unknown	Unk	Not Reported
Ramipril	C	Unknown	Unk	Not Reported
Methotrexate	C	Unknown	25 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	13100036	EXPEDITED (15-DAY)		OT	CA-ROCHE-1877137		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypertension; Limb Discomfort; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Actemra	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Potassium Chloride	C		Not Reported
	Calcium	C	Unknown	Not Reported
	Dorzolamide	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Estrogel	C	Unknown	Not Reported
	Furosemide	C	Unknown	Not Reported
	Valsartan	C	Unknown	Not Reported
	Xalatan	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	13851389	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-069714			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; General Symptom; Neck Pain;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis; Treatment Failure	Methotrexate	S	Unknown	25 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Mobicox	C	Unknown	15 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	13995448	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018261			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Fosamax	S	Unknown	Unk		Not Reported
Enbrel	S	Subcutaneous	Unk		Not Reported
Cortisone Acetate	S	Unknown	Unk		Not Reported
Cimzia	S	Subcutaneous	Unk		Not Reported
Arava	S	Unknown	Unk		Not Reported
Actemra	S	Unknown	Unk		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown			Not Reported
Cortisone Acetate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	14228937	EXPEDITED (15-DAY)		OT	CA-ROCHE-1748896			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown	Therapy Duration: 5 Years		Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Therapy Duration: 577.0 Nos		Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown	Therapy Duration: 577.0 Nos		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Oral			Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 5.0 Years		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 577.0 Nos		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 5 Years		Not Reported

Methotrexate	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 5 Years	Not Reported
Orencia	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 5.0 Years	Not Reported
Remicade	S	Unknown		Not Reported
Simponi	S	Subcutaneous	Therapy Duration: 5.0 Years	Not Reported
Simponi	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Subcutaneous		Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Cortisone	S	Unknown		Not Reported
Desoximetasone	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	15210067	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018304801		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation	Enbrel			S	Subcutaneous	Unk		Unknown
	Methotrexate Sodium			S	Unknown	25 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Intravenous (not	20 Ml, Qwk		Pfizer

Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Methotrexate Sodium		S	Intravenous (not otherwise specified)	20 Mg, Qwk		Pfizer
	Actemra		S	Unknown	Unk		Not Reported
	Arava		S	Oral	20 Mg, Qd		Not Reported
	Humira		S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Humira		S	Subcutaneous	40 Mg, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	Unk		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz		C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	15622519	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557164-00		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Tremor	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

	Methotrexate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Adalimumab	S	Unknown		Not Reported
	Adalimumab	S			Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Pantoprazole Magnesium	C		Enteric Coated	Not Reported
	Tenofovir Disoproxil Fumarate	C	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Zopiclone	C			Not Reported
	Pantoprazole Sodium Anhydrous	C			Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Pantoprazole Bluefish	C			Not Reported
	Tenofovir Disoproxil	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	15708067	EXPEDITED (15-DAY)		HO, OT	US-ACCORD-095250		1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia; Off Label Use	Tacrolimus			S	Transplacental			Not Reported
	Azathioprine			S	Transplacental			Not Reported
	Prednisone			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported
	Betamethasone			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	15851696	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633984-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Joint Arthroplasty; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira	S	Subcutaneous		Not Reported
	Apo-Hydroxyquine	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported
	Methotrexate	C	Subcutaneous	0.8 Ml	Not Reported
	Methotrexate	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	15851869	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2634031-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	15948997	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-049912			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Orencia			S	Unknown	125 Milligram, Qwk, 7 Months		Bristol Myers Squibb
	Cyclosporine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tofacitinib			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not	Unk		Not Reported

			otherwise specified)		
	Ciclosporin	S	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Gabapentin	C	Oral	400 Milligram, Tid	Not Reported
	Tylenol Arthritis	C	Unknown	2 Tab, Qid	Not Reported
	Tylenol Arthritis	C	Unknown	650 Milligram, 4 Every 1 Day	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	15959671	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1012950			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Nausea; Product Label Confusion; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cimzia			C	Subcutaneous			Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	16470169	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP016509		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Ciprofloxacin			S	Unknown	Unk		Apotex
	Clindamycin			S	Unknown			Not Reported
	Enalapril			S	Unknown			Apotex
	Hydrochlorothiazide			S	Unknown			Apotex
	Losartan			S	Unknown	Unk		Apotex
	Hydralazine			S	Unknown			Apotex
	Moxifloxacin			S	Unknown	Unk		Apotex
	Pantoprazole			S	Unknown			Apotex
	Penicillin			S	Unknown	Unk		Apotex
	Metoprolol			S	Unknown			Not Reported
	Cefalexine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Arava			S	Unknown	Unk		Not Reported
	Biaxin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Celebrex			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Levaquin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Unk		Not Reported
	Pariet			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Avelox			S	Unknown	Unk		Not Reported
	Penicilin G			S	Unknown	Unk		Not Reported

Penicillin Nos	S	Unknown	Unk		Not Reported
Esomeprazole	C	Unknown	Unk		Not Reported
Gold	C	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk		Not Reported
Iron Sucrose	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown			Not Reported
Cipro /00697201/	C	Unknown			Not Reported
Venofer	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	16527868	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555951-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Solution-Dosage Form (Form Of Administration)		Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

Sulfasalazine	S	Unknown		Not Reported
Rituximab	S	Intravenous drip		Not Reported
Prednisone	C	Unknown		Not Reported
Simponi	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported
Arava	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	16537815	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP017574		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Azathioprine			S	Unknown	Unk		Apotex
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Cyclosporine			S	Oral	Unk		Apotex
	Actemra			S	Intravenous (not otherwise specified)	640 Mg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	640 Mg, Q.Wk.		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Certolizumab Pegol			S	Unknown	200 Mg, Unk		Not Reported
	Certolizumab Pegol			S				Not Reported
	Ciclosporin			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Q.Wk.		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.Wk.		Not Reported

Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Unknown	400 Mg, Q.Wk.	Not Reported
Hydroxychloroquine /00072603/	S	Unknown	Unk	Not Reported
Imuran /00001501/	S	Unknown	Unk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
Lyrica	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous drip	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Azathioprine	S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.	Not Reported
Azathioprine	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Piroxicam	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	16584896	EXPEDITED (15-DAY)		OT	PHHY2019CA120870			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Lower Respiratory Tract Infection; Malaise; Pain; Thyroid Disorder;	Cosentyx			S	Subcutaneous	150 Mg, Qw		Novartis
	Cosentyx			S	Subcutaneous	150 Mg, Qmo		Novartis

Upper Respiratory Tract Infection	Cosentyx	S	Subcutaneous	150 Mg, Qmo	Novartis
	Cosentyx	S	Unknown	Unk	Novartis
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Humira	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	Unk	Not Reported
	Aleva	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17624677	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-028539		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Increased; Joint Swelling; Renal Disorder	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Atenolol			C	Unknown	50 Milligram		Not Reported
	Cozaar			C	Unknown	25 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17661978	EXPEDITED (15-DAY)		DS, OT	BR-ADVANZ PHARMA-202003002616			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bedridden; Blindness; Cardiac Disorder; Coma; Corneal Disorder; Drug Dependence; Gait Inability; General Physical Health Deterioration; Renal Disorder; Seizure; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	Unk, Qod Tablet		Concordia
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17662028	EXPEDITED (15-DAY)			BR-ADVANZ PHARMA-202003002623			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Therapeutic Response Unexpected	Hydroxychloroquine			S	Oral	1 Dosage Form, Qd, Coated Tablet		Concordia
	Puran T4			C		Unk		Not Reported
	Pregabalin			C		50 Mg		Not Reported
	Pregabalin			C				Not Reported
	Pregabalin			C				Not Reported
	Pregabalin			C				Not Reported
	Alektos			C		20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17703460	EXPEDITED (15-DAY)		DS, LT, OT	FR-AUROBINDO-AUR-APL-2020-020222		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Azithromycin			S	Oral	250 Milligram, Once A Day		Aurobindo
	Nivaquine			S	Oral	200 Milligram, Once A Day (2-3 Cp Per Day)		Not Reported
	Plaquenil			S	Oral	400 Milligram, Once A Day (2-3 Tsp Per Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17727115	EXPEDITED (15-DAY)		HO, LT, OT	FR-ADVANZ PHARMA-202004004354			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Off Label Use; Pneumonia; Rhabdomyolysis; Rhabdomyolysis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		400 Mg, Qd, Film-Coated Tablet		Concordia
	Piperacillin			C		Unk		Not Reported
	Amphotericine B			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17732668	EXPEDITED (15-DAY)		LT, OT	JP-PFIZER INC-2020168162		38 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Ventricular Fibrillation	Azithromycin			S		500 Mg, Daily		Pfizer
	Dexmedetomidine Hydrochloride			S		Unk		Pfizer
	Hydroxychloroquine			S		400 Mg, Daily		Not Reported
	Favipiravir			C				Not Reported
	Methylprednisolone			C		1 Mg/Kg		Not Reported
	Ceftriaxone			C		2 G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17802741	EXPEDITED (15-DAY)		LT	FR-TEVA-2020-FR-1236294		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Azithromycine Anhydre			S	Oral			Not Reported
	Plaquenil 200 Mg, Comprime Pellicule			S	Oropharingeal	200 Mg		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17831822	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202005005605			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Cough; Covid-19; Dizziness; Dyspnoea; Fatigue; Headache; Hypoxia; Lymphopenia; Myalgia; Off Label Use; Oropharyngeal Pain; Pyrexia	Hydroxychloroquine			S	Unknown	400 Mg, Bid		Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			S	Unknown	9 Mg, Qd		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Losartan			C		25 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17835084	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200529886		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Ankylosing Spondylitis; Asthenia; Asthma; Blood Test Abnormal; Body Temperature Decreased; Bone Lesion; Cataract; Chest Pain; Chills; Condition Aggravated; Contusion; Cough; Deep Vein Thrombosis; Diarrhoea; Dysphonia; Dyspnoea; Fall; Fatigue; Feeling Abnormal; Gastrointestinal Disorder; Gastrointestinal Pain; Heart Rate Increased; Hepatic Enzyme Abnormal; Hypersensitivity; Inappropriate Schedule Of Product Administration; Infection; Influenza; Lethargy; Limb Discomfort; Lower Respiratory Tract Infection; Morton'S Neuralgia; Muscular Weakness; Mycotic Allergy; Nausea; Neuropathy Peripheral; Oral Discomfort; Pain In Extremity; Peripheral Swelling; Productive Cough; Psoriatic Arthropathy; Respiratory Tract Congestion;	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Alendronate Sodium			S	Unknown			Not Reported
	Cosentyx			S	Subcutaneous			Not Reported
	Cosentyx			S	Subcutaneous			Not Reported
	Cosentyx			S	Subcutaneous			Not Reported
	Ergocalciferol			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral	Route Also Mentioned As Subcutaneous.		Not Reported
	Methotrexate			S	Oral	Route Also Mentioned As Subcutaneous.		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral	Route Also Mentioned As Subcutaneous.		Not Reported
	Methotrexate			S	Oral	Route Also Mentioned As Subcutaneous.		Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	Also Mentioned As Intramuscular		Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

Rhinorrhoea; Speech Disorder	Adalimumab	S	Oral	Also Mentioned As Subcutaneous	Not Reported
	Tocilizumab	S	Unknown	Also Reported As One Every Once Week	Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Codeine	S	Unknown		Not Reported
	Etanercept	S	Unknown		Not Reported
	Etanercept	S	Unknown		Not Reported
	Gold Sodium Thiomalate	S	Parenteral		Not Reported
	Gold Sodium Thiomalate	S	Intramuscular		Not Reported
	Abatacept	S	Unknown		Not Reported
	Abatacept	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S			Not Reported
	Naproxen	C	Unknown		Not Reported
	Plaquenil /00072602/	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Budesonide W/Formoterol Fumarate	C	Unknown		Not Reported
	Tramadol	C	Unknown		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Xeljanz	C			Not Reported
	Cyclosporine	C			Not Reported
	Simponi	C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17848603	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202005005603			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cough; Covid-19; Fatigue; Off Label Use; Pyrexia	Hydroxychloroquine		S	Unknown	Unk	Concordia
	Hydroxychloroquine		S			Concordia
	Azithromycin		S	Unknown	Unknown	Not Reported
	Prednisone		S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil		S	Unknown	Unk	Not Reported
	Tacrolimus		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17849010	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-ADVANZ PHARMA-202005005784			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Cough; Covid-19; Fatigue; Off Label Use; Pyrexia	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Azithromycin			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown	Baseline, Duration 60 Months		Not Reported
	Mycophenolic Acid			S	Unknown	Unk		Not Reported
	Belatacept			S	Unknown	Unk, Postponed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17849022	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202005005919			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Diarrhoea; Dyspnoea; Off Label Use; Pyrexia	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			S	Unknown	Unk,Duration 14 Months		Not Reported
	Tacrolimus			S	Unknown	Unk,Duration 14 Months		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17849023	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202005005785			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Covid-19; Off Label Use; Pyrexia	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17849041	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202004004635			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Covid-19; Myalgia; Off Label Use; Pyrexia	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			S	Unknown	Unk,Duration 42 Months		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Azithromycin			S				Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Tacrolimus			S	Unknown	Unk,Duration 42 Months		Not Reported
	Adalimumab			S	Unknown	Unk,Duration 42 Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17849042	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202005005915			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Condition Aggravated; Covid-19; Off Label Use	Hydroxychloroquine			S	Unknown	Tablet		Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S		Decreased Dose		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Tacrolimus			S		Decreased Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17849068	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202005005913			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Myalgia; Off Label Use; Pyrexia	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			S	Unknown	Unk, Duration 38 Months		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Belatacept			S	Unknown	Unk, Duration 38 Months		Not Reported
	Tacrolimus			S	Unknown	Unk, Duration 38 Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17849175	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202005005788			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Covid-19; Diarrhoea; Lung Opacity; Off Label Use; Vomiting	Hydroxychloroquine			S	Unknown	Unknown		Concordia
	Prednisone			S	Unknown	Unk,Duration 80 Months		Not Reported
	Azithromycin			S	Unknown	Unknown		Not Reported
	Tacrolimus			S	Unknown	Unk,Duration 80 Months		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17849374	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202005005916			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Covid-19; Off Label Use; Pyrexia	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			S	Unknown	Unk,Duration 118 Months		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Tacrolimus			S	Unknown	Unk,Duration 118 Months		Not Reported

	Mycophenolate Mofetil	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17857435	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-043559		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1.0 Gram		Not Reported
	Rituximab			S	Unknown	1.0 Gram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Methotrexate			C	Subcutaneous	20 Milligram, Qwk		Not Reported
	Methotrexate			C	Unknown	0.8 Milliliter		Not Reported
	Leflunomide			C	Unknown	20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17857621	EXPEDITED (15-DAY)		DS, HO, OT	CA-APOTEX-2020AP011340			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abscess; Arthralgia;	Azathioprine			S	Unknown	Unk		Apotex

Contraindicated Product Administered; Drug Ineffective; Hepatic Fibrosis; Interstitial Lung Disease; Joint Swelling; Rheumatoid Arthritis; Sepsis; Spinal Cord Infection	Diclofenac		S	Unknown	100 Mg, Qd	Apotex
	Hydroxychloroquine		S	Oral	200 Mg, Bid	Apotex
	Leflunomide		S	Oral	10 Mg, Qd	Apotex
	Naproxen		S	Unknown	Unk	Apotex
	Actemra		S	Unknown	Unk	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Mobicox		S	Unknown	15 Mg, Qd	Not Reported
	Myochrysine		S	Intramuscular	50 Mg, Unk	Not Reported
	Remicade		S	Unknown	Unk	Not Reported
	Vioxx		S	Unknown	25 Mg, Qd	Not Reported
	Xeljanz		S	Oral	5 Mg, Bid	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Methotrexate		C	Intramuscular	Unk, Q.Wk.	Not Reported
	Plaquenil /00072602/		C	Unknown	Unk	Not Reported
	Prednisone		C	Oral	12.5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869186	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP011878		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Liver	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	1 Df, Qd		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk, Q.Wk.		Not Reported
	Aclasta			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported

Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Stenosis; Treatment Failure	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S			Not Reported
	Sulfasalazine	S	Oral	2 G, Qd	Not Reported
	Tramacet	S	Unknown	Unk	Not Reported
	Calcium	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Lorazepam	C	Unknown	1 Mg, Qd	Not Reported
	Lyrica	C	Oral	150 Mg, Bid	Not Reported
	Metformin	C	Unknown	5 Mg, Qd	Not Reported
	Metformin	C	Unknown	500 Mg, Bid	Not Reported
	Methylprednisolone Acetate	C	Intramuscular	40 Mg, Q.M.T.	Not Reported
	Methylprednisolone Acetate	C	Subcutaneous	Unk Unk, Q.M.T.	Not Reported
	Methylprednisolone Acetate	C	Unknown	Unk	Not Reported
	Nortriptyline	C	Unknown	Unk	Not Reported
	Nortriptyline	C	Unknown	20 Mg, Qd	Not Reported
	Nortriptyline	C			Not Reported
	Premarin	C	Unknown	0.625 Mg, Unk	Not Reported
	Risedronate Sodium	C	Unknown	35 Mg, Q.Wk.	Not Reported
	Tylenol /00020001/	C	Unknown	Unk	Not Reported
	Vagifem	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869253	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1244875		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr

Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Actemra	S	Unknown	Not Reported
	Actemra	S		Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Ilaris Single-Use Vial	S	Unknown	Not Reported
	Ilaris Single-Use Vial	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869361	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1244883			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased;	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Treatment Failure	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Prednisone		C	Unknown	20 Milligram Daily;	Not Reported
	Xeljanz		C	Unknown	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869402	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1243575		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869409	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1244882		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Estradiol			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Baclofen			C	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown			Not Reported
	Levaquin			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Xalatan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869413	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1244721		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol	Methotrexate			S	Unknown			Barr

Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Humira	S	Subcutaneous	400 Milligram Daily;	Not Reported
	Enbrel	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Anakinra	C	Unknown		Not Reported
	Ativan	C			Not Reported
	Benadryl	C	Unknown		Not Reported
	Codeine	C	Unknown		Not Reported
	Darifenacin Hydrobromide	C	Unknown		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Dilaudid	C	Unknown		Not Reported
	Furosemide	C			Not Reported
	Hydromorphone	C	Unknown		Not Reported
	Kadian	C			Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Unknown		Not Reported
	Lasix [Furosemide]	C	Unknown		Not Reported
	Loperamide	C	Unknown		Not Reported
	Morphine Sulfate	C	Unknown		Not Reported
	Norflex [Orphenadrine Citrate]	C	Unknown		Not Reported
	Omnaris	C	Unknown		Not Reported
	Oxyneo	C	Unknown		Not Reported
	Pantoloc [Pantoprazole]	C	Unknown		Not Reported

Pantoprazole	C	Unknown	Not Reported
Restasis	C	Unknown	Not Reported
Trimethoprim	C	Unknown	Not Reported
Urispas	C	Unknown	Not Reported
Vagifem	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869512	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-GSH201812-004162			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Blood Urea Increased; Cataract; Cataract; Dermatitis; Diarrhoea; Gastroenteritis; Inflammation; Oedema; Oliguria; Pyrexia; Shock; Steroid Diabetes; Vomiting	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd,Film-Coated Tablet		Concordia
	Prednisolone			S	Oral	25 Mg, Qd		Not Reported
	Prednisolone			S	Oral	40 Mg, Qd		Not Reported
	Prednisolone			S	Oral	35 Mg, Qd		Not Reported
	Prednisolone			S	Oral	30 Mg, Qd		Not Reported
	Prednisolone			S	Oral	25 Mg, Qd		Not Reported
	Prednisolone			S	Oral	22.5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	20 Mg, Qd		Not Reported
	Prednisolone			S	Oral	10 Mg, Qd		Not Reported
	Prednisolone			S	Oral	15 Mg, Qd		Not Reported
	Prednisolone			S	Oral	10 Mg, Qd		Not Reported
	Amitriptyline Hydrochloride			S	Oral	10 Mg, Qd		Not Reported
	Prograf			C		Unk		Not Reported
	Prednisolone			C		Unk		Not Reported
	Amitiza			C		Unk		Not Reported
	Alfacalcidol			C		Unk		Not Reported
	Samtirel			C		Unk		Not Reported
	Nexium			C	Oral	20 Mg, Qd		Not Reported

Menatetrenone	C		Unk		Not Reported
Magmitt	C		Unk		Not Reported
Atorvastatin	C		Unk		Not Reported
Daikenchuto	C		Unk		Not Reported
Odomel	C		Unk		Not Reported
Mucosta	C		Unk		Not Reported
Bayaspirin	C	Oral	100 Mg, Qd		Not Reported
Gatiflo	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869561	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1245278			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869608	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2020AP011695		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide	Alendronate			S	Oral	Unk		Apotex
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex

Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium	S	Unknown	Unk	Apotex
	Folic Acid	S	Unknown	1 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Hydroxychloroquine	S	Oral	400 Mg, Qd	Apotex
	Hydroxychloroquine	S	Oral	Unk	Apotex
	Leflunomide	S	Oral	Unk	Apotex
	Methotrexate	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate	S	Oral	25 Mg, Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	10 Mg, Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Mg, Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Oral	400 Mg, Qd	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Oral	1000 Mg, Bid	Not Reported

Sulfathalidine	S	Oral	1000 Mg, Bid		Not Reported
Sulfathalidine	S	Oral	500 Mg, Unk		Not Reported
Tofacitinib	S	Unknown	5 Mg, Bid		Not Reported
Tofacitinib Citrate	S	Unknown	5 Mg, Bid		Not Reported
Topicort /00370301/	S	Cutaneous	Unk		Not Reported
Atasol /00020001/	C	Unknown	Unk		Not Reported
Salazopyrin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869695	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3430358-00		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869724	EXPEDITED (15-DAY)		HO	ES-ROCHE-2613253		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis; Off Label Use; Product Use In Unapproved Indication	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Metamizol [Metamizole]			S	Intravenous (not otherwise specified)			Not Reported

	Hidroxicloroquina Sulfato	S	Oral		Not Reported
	Paracetamol	S	Intravenous (not otherwise specified)	Dose Reduced	Not Reported
	Azitromicina	S	Oral		Not Reported
	Azitromicina	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869727	EXPEDITED (15-DAY)		OT	CA-ROCHE-2611690			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Nodule; Off Label Use; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tenosynovitis; Therapeutic Response Decreased; Tooth Disorder; Tooth Infection; Weight Decreased	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Naproxen			C				Not Reported
	Risedronate Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869741	EXPEDITED (15-DAY)		OT	ES-ROCHE-2610743		61 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Hypofibrinogenaemia; Melaena; Sepsis	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S				Not Reported

	Hidroxicloroquina Sulfato	S	Oral	Not Reported
	Hidroxicloroquina Sulfato	S		Not Reported
	Dexametasona [Dexamethasone]	C	Intravenous (not otherwise specified)	Not Reported
	Dexametasona [Dexamethasone]	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869887	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2020-027171		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Tinea; Bone Density Decreased; Cataract; Cellulitis; Contusion; Drug Ineffective; Fatigue; Glucose Tolerance Impaired; Herpes Zoster; Hyperlipidaemia; Hypertension; Impaired Quality Of Life; Impaired Work Ability; Infection Susceptibility Increased; Inhibitory Drug Interaction; Insomnia; Oral Herpes; Poor Quality Sleep; Purpura; Skin Disorder; Weight Increased	Amlodipine			S	Unknown	Unk		Aurobindo
	Lidocaine			S	Intravenous (not otherwise specified)	Unk		Aurobindo
	Lidocaine			S	Topical	Unk		Aurobindo
	Montelukast			S	Unknown	Unk		Aurobindo
	Pregabalin Capsules			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Apremilast			S	Unknown	Unk		Not Reported
	Bumetanide			S	Unknown	Unk		Not Reported
	Capsaicin			S	Topical	Unk		Not Reported
	Cimetidine			S	Unknown	Unk		Not Reported
	Clonidine			S	Unknown	Unk		Not Reported
	Diltiazem			S	Unknown	Unk		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Ibudilast			S	Unknown	Unk		Not Reported
	Ketamine			S	Topical	Unk		Not Reported
	Ketamine			S	Oral	Unk		Not Reported
	Ketamine			S	Intravenous (not	Unk		Not Reported

		otherwise specified)		
Lithium Carbonate	S	Unknown	Unk	Not Reported
Magnesium	S	Unknown	Unk	Not Reported
Magnesium	S			Not Reported
Memantine	S	Unknown	Unk	Not Reported
Metoprolol	S	Unknown	Unk	Not Reported
Mexiletine	S	Unknown	Unk	Not Reported
Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
N-Acetylcysteine	S	Unknown	Unk	Not Reported
Naltrexone Hydrochloride	S	Unknown	4.5 Milligram, Once A Day	Not Reported
Palmitoylethanolamide	S	Unknown	Unk	Not Reported
Pentoxifylline	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	5 Milligram	Not Reported
Prednisone	S	Unknown	13 Milligram	Not Reported
Prednisone	S	Unknown	95 Milligram, Once A Day	Not Reported
Prednisone	S	Unknown	85 Milligram, Once A Day	Not Reported
Spironolactone	S	Unknown	Unk	Not Reported
Vitamin B 12	S	Unknown	Unk	Not Reported
Vitamin B 12	S			Not Reported
Vitamin C	S	Unknown	Unk	Not Reported
Calcitonin	C	Unknown	Unk	Not Reported
Ezetimibe	C	Unknown	Unk	Not Reported
Trazodone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869891	EXPEDITED (15-DAY)		HO, OT	US-VELOXIS PHARMACEUTICALS-2020VELUS-000533		1 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia	Envarsus Xr			S	Transplacental			Veloxis Pharmaceuticals

	Hydroxychloroquine	S	Transplacental		Not Reported
	Prednisone	S	Transplacental		Not Reported
	Azathioprine	S	Transplacental		Not Reported
	Betamethasone	C	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869893	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3433945-00		70 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia	Kaletra 200/50			S	Oral			Not Reported
	Atorvastatina Mabo			S	Oral	Atorvastatina Mabo 40 Mg Comprimidos Recubiertos Con Pelicula Efg, 28 Comprimidos		Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869907	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-027340		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Atypical Mycobacterial Infection; Bacterial Infection; Bronchiectasis; C-Reactive Protein Increased; Cellulitis; Chest Pain; Cough; Crystal Arthropathy; Diarrhoea; Drug Ineffective; Drug Intolerance; Erythema; Gout; Grip Strength Decreased; Infective Exacerbation Of Bronchiectasis; Ligament Sprain; Lung Disorder;	Azithromycin			S	Unknown	Unk		Aurobindo
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methylprednisolone Acetate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

Middle Lobe Syndrome; Nightmare; Oropharyngeal Pain; Osteoarthritis; Pain; Paraesthesia; Peripheral Swelling; Rash; Rheumatoid Arthritis; Rheumatoid Factor; Synovitis; Underweight; Upper Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17869943	EXPEDITED (15-DAY)		HO	CA-ROCHE-2611504		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Rituximab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17870632	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP011672		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand	Apo-Prednisone			S	Unknown	5 Mg, Unk		Apotex
	Cetirizine			S	Unknown	Unk		Apotex
	Diclofenac			S	Unknown	Unk		Apotex
	Folic Acid			S	Unknown	500 Mg, Unk		Not Reported

Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Methotrexate	S	Oral	25 Mg, Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Oral	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	1 G, Bid	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17870785	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202005005634			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Off Label Use	Hydroxychloroquine			S	Unknown	400 Mg (Loading Dose)		Concordia
	Hydroxychloroquine			S		200 Mg, Bid		Concordia
	Ascorbic Acid			S	Intravenous (not otherwise specified)	6 G, Bid		Not Reported
	Azithromycin			S	Oral	500 Mg, Qd		Not Reported

	Azithromycin	S		500 Mg, Qd (Orogastric Tube)	Not Reported
	Ceftriaxone	S	Intravenous (not otherwise specified)	1 G, Qd	Not Reported
	Tocilizumab	S		8 Mg/Kg (567mg) One Dose	Not Reported
	Tocilizumab	S		Another Dose (Unknown Details)	Not Reported
	Remdesivir	C		200 Mg On Day 10 (Discontinued On 12 Day)	Not Reported
	Ceftazidime	C	Intravenous (not otherwise specified)	1 G, Tid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17870803	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1244971		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash; Urticaria	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Atenolol			C	Oral	50 Milligram Daily;		Not Reported
	Hydrochlorothiazide			C	Unknown	25 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17870831	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1244963			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Disorder; Hepatotoxicity; Pain	Methotrexate	S	Unknown	Barr
	Arava	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17870906	EXPEDITED (15-DAY)		LT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-044055			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Pain; Therapeutic Product Effect Decreased	Orencia			S	Unknown	750 Milligram, Q4wk		Bristol Myers Squibb
	Adalimumab			S	Subcutaneous	40.0 Milligram, Qwk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Oral	200 Milligram, 2 Every 1 Day		Not Reported
	Kevzara			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Q4wk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Oral	5.0 Milligram, 2 Every 1 Day		Not Reported
	Rabeprazole Sodium			C	Oral	20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871132	NON-EXPEDITED			US-AMGEN-USASP2020086744		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Exfoliation; Skin Reaction	Otezla			S	Oral	30 Milligram, Bid		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871133	EXPEDITED (15-DAY)		OT	IT-AMNEAL PHARMACEUTICALS-2020-AMRX-01621		34 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Capillary Leak Syndrome	Hydroxychloroquine Sulfate			S	Unknown	Unk		Amneal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871181	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020218407			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Actemra			S		Unk		Not Reported
	Arava			S	Oral	20 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871186	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020219909			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Erythema; Hepatitis Acute; Hypersensitivity; Oedema; Skin Plaque; Urticaria	Methotrexate Sodium		S		15 Mg	Pfizer
	Arava		S	Unknown	Unk	Not Reported
	Humira		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	200 Mg	Not Reported
	Orencia		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871194	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020218406		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lung Neoplasm Malignant; Osteoarthritis; Pancytopenia	Methotrexate Sodium			S		Unk		Pfizer
	Cimzia			S	Subcutaneous	Unk (Therapy Duration: 365.0, As Reported)		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Plaquenil Sulfate			S		300 Mg, 1x/Day		Not Reported
	Elavil [Amitriptyline Hydrochloride]			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Lansoprazole			C		30 Mg, 1x/Day		Not Reported
	Tylenol [Paracetamol]			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871202	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020219912		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Deformity; Drug Ineffective; Rheumatoid Arthritis	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, 1x/Day		Not Reported

	Prevnar 13	C	Unknown	Unk, Single	Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day (1 Every 12 Hours)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871286	EXPEDITED (15-DAY)		HO, LT, OT	TR-SA-2020SA143578			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Off Label Use; Sars-Cov-2 Test Positive	Prednisone			S	Oral	10 Mg, Qd		Not Reported
	Hydroxychloroquine			S		Unk		Sanofi
	Hydroxychloroquine			S				Sanofi
	Thymoglobulin			S		Unk		Sanofi
	Mycophenolate Mofetil			S	Oral	Unk		Not Reported
	Tacrolimus			S	Oral	Unk		Not Reported
	Nebivolol			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871321	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1245871		73 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Mg Every 12 Hours Followed By 200 Mg Every 12 Hours		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Ceftriaxona (501a)			S	Unknown	2 Gram		Not Reported
	Ceftriaxona (501a)			S				Not Reported
	Hbpmin - Heparina De Bajo Peso Molecular (Hbpm) (Sin Especificar)			C				Not Reported
	Lopinavir/Ritonavir Accord 200			C	Oral	400 Mg Every 12 Hours, 1		Not Reported

	Mg/ 50 Mg Comprimidos Recubiertos Con P		Dosage Form	
	Lopinavir/Ritonavir Accord 200 Mg/ 50 Mg Comprimidos Recubiertos Con P	C		Not Reported
	Sintrom	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871507	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020222720		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Off Label Use; Product Use In Unapproved Indication; Product Use Issue	Azithromycin			S	Oral	Unk		Pfizer
	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Kaletra			S	Oral	2 Df, Every 12 Hours		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871811	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020218337			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Contraindicated Product Administered; Drug Intolerance; Maculopathy; Thrombocytopenia	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine Sulfate			S				Not Reported
	Enbrel			C		50 Mg, 1x/Day		Not Reported
	Xeljanz			C	Oral	5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872148	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020222841		33 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia; Liver Disorder; Off Label Use; Product Use In	Azithromycin			S	Oral	Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported

Unapproved Indication	Ceftriaxone		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Kaletra		S	Oral	2 Df, 2x/Day (Every 12 Hours)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872371	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3433676-00		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Sinus Bradycardia	Kaletra 200/50			S	Oral			Not Reported
	Dolquine			S	Oral	200 Mg Comprimidos Recubiertos, 30 Comprimidos		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872623	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609857		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Flushing; Heart Rate Decreased; Herpes Zoster; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Diphenhydramine Hydrochloride			C				Not Reported

Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Ferrous Gluconate	C	Unknown		Not Reported
	Folic Acid	C			Not Reported
	Lasix [Furosemide]	C			Not Reported
	Methylprednisolone	C			Not Reported
	Naprosyn [Naproxen]	C			Not Reported
	Oxycontin	C			Not Reported
	Oxyneo	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872683	EXPEDITED (15-DAY)		OT	FR-SA-2020SA145735			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease; Emphysema	Plaquenil			S	Oral	200 Mg, Qd		Sanofi
	Bromazepam			S	Oral	Not Speciffied		Not Reported
	Methotrexate			S	Oral	6 Df, Qw		Not Reported
	Naproxen Sodium			S	Oral	1 Tablet In The Morning And Evening For 7 Days In Case Of Severe Pain		Not Reported
	Omeprazole			S	Oral	20 Mg		Not Reported
	Duloxetine Hydrochloride			S	Oral	60 Mg		Not Reported
	Fluoxetine Hydrochloride			S	Oral	20 Mg		Not Reported
	Imovane			S	Oral	7.5 Mg, Qd		Not Reported
	Doliprane			S	Oral	1000 Mg 3x/Day On An Ad Hoc Basis		Not Reported
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Enbrel			S	Subcutaneous	25 Mg, Qw		Not Reported
	Vitamine D3 Bon			S	Oral	1 Df, Qm		Not Reported
	Izalgi			S	Oral	Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872709	EXPEDITED (15-DAY)		HO, OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2020VAL000470			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Tinea; Bone Density Decreased; Cataract; Cellulitis; Contusion; Drug Ineffective; Fatigue; Glucose Tolerance Impaired; Herpes Zoster; Hyperlipidaemia; Hypertension; Impaired Quality Of Life; Impaired Work Ability; Infection Susceptibility Increased; Inhibitory Drug Interaction; Insomnia; Oral Herpes; Poor Quality Sleep; Purpura; Skin Disorder; Weight Increased	Bumetanide			S	Unknown	Unk		Validus
	Pentoxifylline			S	Unknown	Unk		Validus
	Diltiazem Hydrochloride			S	Unknown	Unk		Not Reported
	Capsaicin			S	Topical	Unk		Not Reported
	Lithium Carbonate			S	Unknown	Unk		Not Reported
	Amitriptyline Hydrochloride			S	Unknown	Unk		Not Reported
	Magnesium Gluconate			S	Unknown	Unk		Not Reported
	Magnesium Gluconate			S				Not Reported
	Amlodipine Besilate			S	Unknown	Unk		Not Reported
	Cimetidine			S	Unknown	Unk		Not Reported
	Clonidine			S	Unknown	Unk		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Apremilast			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Ibudilast			S	Unknown	Unk		Not Reported
	Trazodone			C		Unk		Not Reported
	Ezetimibe			C		Unk		Not Reported
	Calcitonin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17873019	EXPEDITED (15-DAY)		DE, HO	CA-ROCHE-2610855			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Death; Deep Vein Thrombosis;	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported

Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Rituximab	S	Unknown		Not Reported
	Rituximab	S			Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S			Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S			Not Reported
	Cannabis Sativa	S	Unknown		Not Reported
	Cannabis Sativa	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Gold	S			Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Ilaris	S	Unknown	Single Use	Not Reported
	Ilaris	S	Subcutaneous	Single Use Powder For Solution	Not Reported
	Ilaris	S	Intravenous (not otherwise specified)		Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported

Methotrexate	S	Unknown	Not Reported
Minocycline	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Oxycodone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Kineret	C	Unknown	Not Reported
Lyrica	C	Oral	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C	Oral	Not Reported
Prednisone	C	Unknown	Not Reported
Urelumab	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17873036	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-044930			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported

Arthritis	Apo-Leflunomide		S	Unknown	Unk	Not Reported
	Enbrel		S	Subcutaneous	Unk	Not Reported
	Humira		S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulphate		S	Unknown	Unk	Not Reported
	Leflunomide		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17873322	EXPEDITED (15-DAY)		DE, HO, OT	ES-ABBVIE-20K-144-3435672-00		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Cardiac Failure; Death; Escherichia Urinary Tract Infection; Renal Failure; Respiratory Disorder; Respiratory Distress	Lopinavir/Ritonavir			S	Oral			Not Reported
	Lopinavir/Ritonavir			S				Not Reported
	Lopinavir/Ritonavir			S				Not Reported
	Azithromycin			S	Unknown			Not Reported
	Azithromycin			S				Not Reported
	Azithromycin			S				Not Reported
	Methylprednisolone Acetate			S	Unknown	Lower Doses (+/- 1mg/Kg Per Day)		Not Reported
	Methylprednisolone Acetate			S	Unknown			Not Reported
	Methylprednisolone Acetate			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ertapenem Sodium			S	Unknown			Not Reported